HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
OCTOBER 26, 2016
APPLICATION SUMMARY

NAME OF PROJECT:	AxelaCare Health Solutions
PROJECT NUMBER:	CN1606-022
ADDRESS:	5100 Poplar Avenue, 27th Floor, Suite 2739 Memphis, (Shelby County), Tennessee 38137
LEGAL OWNER:	AxelaCare Health Solutions, LLC c/o Office of General Counsel, AxelaCare, 15529 C College Blvd. Lenexa, (Johnson County), Kansas 66219
OPERATING ENTITY:	Not Applicable
CONTACT PERSON:	John Wellborn 615-665-2022
DATE FILED:	June 14, 2016
PROJECT COST:	$69,628
FINANCING:	Cash Reserves
PURPOSE FOR FILING:	Establishment of a Home Care Organization and the Initiation of Home Health Services limited to Provision and Administration only of Home Infusion of Immune Globulin Pharmaceuticals

DESCRIPTION:

AxelaCare Health Solutions is requesting approval to establish a home care organization and initiate home health services limited to the home infusion of immune globulin pharmaceuticals in 21 West Tennessee counties. The principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis (Shelby County) Tennessee.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

1. **Determination of Need:** In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. This 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed Service Area.

The applicant applied the 1.5 percent need formula to the proposed service area population.

It appears this criterion has been met.

2. The need for home health services should be projected three years from the latest available year of final JAR data.

The applicant projected need three years from the 2015 final JAR.

It appears this criterion has been met.

3. The use rate of existing home health agencies in each county of the Service Area will be determined by examining the latest utilization rate as calculated from the JARs of existing home health agencies in the Service Area. Based on the number of patients served by home health agencies in the Service Area, estimation will be made as to how many patients could be served in the future.

Following Steps 1-3 above the Department of Health report that is based on 2015 data, indicates that 24,625 service area residents will need home health care in 2018; however 39,748 patients are projected to be served in 2018 resulting in a net excess of 15,125 patients.

Since projected patients to be served exceed the calculated need, it appears this criterion has not been met.

4. **County Need Standard:** The applicant should demonstrate that there is a need for home health services in each county in the proposed Service Area by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed

Service Area attempted to find appropriate home health services but were not able to secure such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

The applicant submitted support letters from two specialty medical practices located in Memphis (Shelby County), Tennessee, and two specialty medical practices located in Washington, DC (that each has one patient that reside in West Tennessee), and a Pharmacist located in Hamilton County (outside of the proposed service area).

It appears this criterion has been met.

5. **Current Service Area Utilization:** The applicant should document by county: a) all existing providers of home health services within the proposed Service Area; and b) the number of patients served during the most recent 12-month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use final data provided by the JARs maintained by the Tennessee Department of Health. In each county of the proposed Service Area, the applicant should identify home health agencies that have reported serving 5 or fewer patients for each of the last three years based on final and available JAR data. If an agency in the proposed Service Area who serves few or no patients is opposing the application, that opponent agency should provide evidence as to why it does not serve a larger number of patients.

The applicant provided tables on pages 44a-44g of the application that includes all existing home health providers and the number of patients served for the latest three JAR reporting years.

The applicant identified six home health agencies that have served five or fewer patients in the service area in 2015. The table is located in Supplemental #1 Table Two.

It appears this criterion has been met.

6. **Adequate Staffing:** Using TDH Licensure data, the applicant should document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and document that such personnel are available to work in the proposed Service Area. The applicant should state the percentage of qualified personnel directly employed or employed through a third party staffing agency.

AxelaCare has experience in recruiting, employing, and training skilled nursing staff to specifically manage IVIG care in homes. The proposed project will require between 3 and 4 skilled nurses with competencies in infusion care. All the nurses will be directly employed by AxelaCare.

It appears this criterion has been met.

7. **Community Linkage Plan:** The applicant should provide a community linkage plan that demonstrates factors such as, but not limited to, referral arrangements with appropriate health care system providers/services (that comply with CMS patient choice protections) and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems. A new provider may submit a proposed community linkage plan.

The applicant's primary linkage plan will include referring specialty physicians with the secondary linkage plan including hospital discharge planners and medical staff.

It appears this criterion has been met.

8. **TennCare Managed Care Organizations (MCOs) and Financial Viability:** Given the time frame required to obtain Medicare certification, an applicant proposing to contract with the Bureau of TennCare's MCOs should provide evidence of financial viability during the time period necessary to receive such certification. Applicants should be aware that MCOs are under no obligation to contract with home care organizations, even if Medicare certification is obtained, and that Private Duty Services are not Medicare certifiable services. Applicants who believe there is a need to serve TennCare patients should contact the TennCare MCOs in the region of the proposed Service Area and inquire whether their panels are open for home health services, as advised in the notice posted on the HSDA website, to determine whether at any given point there is a need for a provider in a particular area of the state; letters from the TennCare MCOs should be provided to document such need. See Note 2 for additional information.

Applicants should also provide information on projected revenue sources, including non-TennCare revenue sources.

The applicant will not participate in the Medicare and TennCare/Medicaid programs. The commercial payor will represent $254,016 or 98% of total revenue.

It appears this criterion has been met.

9. **Proposed Charges:** The applicant's proposed charges should be reasonable in comparison with those of other similar agencies in the Service Area or in adjoining service areas. The applicant should list:

a. The average charge per visit and/or episode of care by service category, if available in the JAR data.

The applicant provided 2015 JAR charge data per visits and hour on page 34 of the application.

It appears this criterion has been met.

b. The average charge per patient based upon the projected number of visits and/or episodes of care and/or hours per patient, if available in the JAR data.

Infusion-specific comparable charge data from the application Coram/CVS Specialty Infusion Services (CN1406-018) is the only infusion specialty charge data available. In the application Coram projected its charges for specialty infusion at $290-$348. The applicant projected their charge at $240.

It appears this criterion has been met.

10. **Access:** In concert with the factors set forth in HSDA Rule 0720-11-.01(1) (which lists those factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant that is able to show that there is limited access in the proposed Service Area for groups with special medical needs such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. Pediatrics is a special medical needs population, and therefore any provider applying to provide these services should demonstrate documentation of adequately trained staff specific to this population's needs with a plan to provide ongoing best practice education. For purposes of this Standard, an applicant should document need using population, service, special needs, and/or disease incidence rates. If granted, the Certificate of Need should be restricted on condition, and thus in its licensure, to serving the special group or groups identified in the application. The restricting language should be as follows: CONDITION: Home health agency services are limited to (*identified specialty service group*); the expansion of service beyond (*identified specialty service group*) will require the filing of a new Certificate of Need application. Please see Note 3 regarding federal law prohibitions on discrimination in the provision of health care services.

If granted, the applicant requests a CON limited to home health services providing infusion of immune globulin pharmaceuticals only.

It appears this criterion has been met.

11. **Quality Control and Monitoring:** The applicant should identify and document its existing or proposed plan for data reporting (including data on patient re-admission to hospitals), quality improvement, and an outcome and process monitoring system (including continuum of care and transitions of care from acute care facilities). If applicable, the applicant should provide documentation that it is, or that it intends to be, fully accredited by the Joint Commission, the Community Health Accreditation Program, Inc., the Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS.

The applicant is accredited by The Joint Commission. AxelaCare's Specialty Pharmacy Program is accredited by URAC (Utilization Review Accreditation Program).

It appears this criterion has been met.

12. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant will continue to provide all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested.

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Application Synopsis

AxelaCare Health Solutions seeks to establish an integrated home infusion program across all of West Tennessee for patients utilizing AxelaCare infusion medications for immune globulin. The principal office will be located in Memphis (Shelby County) with at least one nurse who lives in the Jackson (Madison County), TN area to serve the easternmost counties in the 21 county service area. All patient pharmaceuticals, supplies, and equipment needed for home infusion of immune globulin medications will be direct shipped to patients from the applicant's pharmacy located in Kansas. The target population are individuals under the age of 65.

Immune Globulin is a medicine that contains antibodies, which are tiny proteins that patrol the blood stream to alert the body of germs, which the body then can destroy through complex immune system responses. Referring medical specialties (neurologists, immunologists, oncologists, etc.) will prescribe immune globulin therapy to treat patients with challenging immune system disorders. Examples of disorders that often require immune globulin (IVIG) therapy are located on pages 16-18 of the application. IVIG infusion requires significant nursing experience and training and requires the nurse to spend long hours of monitoring with a patient over a prolonged treatment period. An overview of AxelaCare's program for delivery of home infusion care for IVIG patients is located on pages 13-18 of the application.

The payor types of home health patients to be served by the applicant will be privately insured, self-pay, or medically indigent patients under the age of 65 who do not qualify for Medicare and Medicaid services. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid.

This CON will be followed by two or more CON applications requesting similar authorization for Middle and East Tennessee with the applicant's objective of becoming one of the few statewide providers of home infusion of immune globulin medications. If approved, the AxelaCare Health Solutions expects to initiate service on January 1, 2017.

Facility Information

- The applicant will be located in a 149 SF suite in the Clark Tower office building in Memphis (Shelby County), TN.
- The home office will be used only by the agency's administrative staff which will consist of one member.
- There is no construction, renovation or modification required to implement the proposed project.

Ownership

- AxelaCare Health Solutions, LLC is an active Tennessee registered limited liability company formed May 5, 2008.
- AxelaCare Health Solutions, LLC is ultimately owned by UnitedHealth Group Inc.
- The applicant provides a legal entity and organization chart in Attachment A.4-Ownership.

NEED

Project Need

- The applicant indicates physicians and their patients need a provider who can provide the following: 1) start infusions in the patient's home without delay, 2) provide highly skilled nurses specializing in specialty infusion; 3) provide superior communication to the physician and pharmacist working with the patient; and 4) serve West Tennessee patients who live in remote areas.

- Patient receiving first dose infusion services at home may reduce length of stay at the hospital and reduce hospital costs.

- Patients that are required to commute for infusion services are at risk of contracting opportunistic infections through exposure to other persons.

- Commuting is less convenient and typically more expensive for the patient than obtaining care in one's home.

Service Area Demographics

- The total population of the 21 county service area is estimated at 1,622,273 residents in calendar year (CY) 2016 increasing by approximately 2.4% to 1,660,459 residents in CY 2020.
- The overall statewide population is projected to grow by 4.3% from 2014 to 2018.
- The proposed service area 65 and under population will increase 0.2% from 1,385,433 in 2016 to 1,388,439 in 2020. The statewide 65 and under

population will increase 2.1% between 2016 and 2020 from 5,720,489 to 5,841,736.

- The latest 2016 percentage of the service area population enrolled in the TennCare program is approximately 27.4%, as compared to the statewide enrollment proportion of 22.9%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

The 21 counties that consist of the applicant's proposed service area are presented in the table below:

Benton	Carroll	Chester	Crockett
Decatur	Dyer	Fayette	Gibson
Hardeman	Hardin	Haywood	Henderson
Henry	Lake	Lauderdale	Madison
McNairy	Obion	Shelby	Tipton
Weakley			

Source: CN1606-022

Service Area Historical Utilization

Department of Health Joint Annual Reports for 2015 identified 52 existing home health agencies that reported utilization in at least one of the 21 service area counties. Home health utilization data indicated 40,070 patients were served in 2013 decreasing 2.3% to 39,117 patients in 2015.

Applicant's Historical and Projected Utilization

- Since this is a new proposed home health provider, there is historical data available for the applicant.
- 45 patients are projected in Year 1 and 65 patients in Year 2 representing 1,080 and 1,560 skilled nursing visits, respectively.

ECONOMIC FEASIBILITY

Project Cost

Major costs of the $69,628 total estimated project cost are:

- Legal, Administrative, Consultants Fee- $50,000 or 71.8% of total cost.
- Pro-rated Lease- $11,628 or 16.7% of total cost.
- Moveable Equipment-$5,000 or 7.2% of total cost.

For other details on Project Cost, see the revised Project Cost Chart on page 48 of the application.

Financing

- A June 10, 2016 letter from AxelaCare Holdings, Inc.'s Controller confirms the availability of cash reserves from a cash transfer from United Health Group, Inc. to fund the proposed project.

- United Health Group's audited financial statements for the period ending December 31, 2015 indicates $10,923,000,000 in cash and cash equivalents, total current assets of $31,639,000,000 total current liabilities of $42,898,000,000 and a current ratio of .74:1.
- In the supplemental response, the applicant provided unaudited financial documents for the period ending March 31, 2016 that reflects $13,014,000,000 in cash and short-term investments, $33,745,000,000 in current assets, and total current liabilities of $23,958,000,000 and a current ratio of 1.40:1.

Current ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Historical Data Chart

- Since this is a new proposed home health provider, a historical data chart was not available.

Projected Data Chart

The applicant submitted the following three Projected Data Charts.

1) AxelaCare West Pharmaceuticals Only

- The Projected Data Chart for the Pharmaceuticals only reflects $4,320,000 in total gross revenue on 1,080 patient visits/45 patients during the first year of operation and $6,240,000 on 1,560 patient visits/65 patients in Year Two (approximately $1,560 per visit or $5,760 per patient).
- Net operating income is estimated at $669,727 in Year One increasing to $1,088,735 in Year Two.

2) Nursing and Home Office Only-Pharmaceuticals Excluded

- The Projected Data Chart for the Nursing and Home Office only reflects $259,200 in total gross revenue on 1,080 patient visits/45 patients during the first year of operation and $374,400 on 1,560 patient visits/65 patients in Year Two (approximately $240 per visit or $5,740 per patient).
- Net operating income is estimated at ($150,413) in Year One decreasing to ($170,587) in Year Two.

3) Consolidated Operations, Nursing Home Office, and Pharmaceuticals

- The Projected Data Chart for the Nursing Home Office and Pharmaceuticals combined reflects $4,579,200 in total gross revenue on 1,080 patient visits/45 patients during the first year of operation and

$6,614,000 on 1,560 patient visits/65 patients in Year Two (approximately $1,560 per visit or $101,760 per patient).
- Net operating income is estimated at $519,313 in Year One increasing to $927,148 in Year Two.

Charges
In Year One of the proposed project, the average charge per case are as follows:

West Tennessee Nursing Operations Only
- The proposed average gross charge is $5,760.00/patient case
- The average deduction is $173.00/patient case, producing an average net charge of $5,587/patient case.

Combined West Tennessee Nursing and Out of State Pharmaceutical Operations
- The proposed average gross charge is $101,760.00/patient case
- The average deduction is $3,052.00/patient case, producing an average net charge of $98,707/patient case.

Medicare/TennCare Payor Mix
- The applicant will not participate in the Medicare and TennCare/Medicaid programs.
- The commercial payor will represent $254,016 or 98% of total revenue.
- Charity care will represent $5,184 or 2% of total revenue.

PROVIDE HEALTHCARE THAT MEETS APPROPRIATE QUALITY STANDARDS

Licensure
- The applicant will seek licensure from the Tennessee Department of Health, Board for Licensing Healthcare Facilities.
- AxelaCare has a Tennessee non-resident pharmacy license and its associated Sterile Compounding License issued by the Department of Health.
- The AxelaCare Tennessee non-resident pharmacy license allows the shipment of immune globulin product to patient homes in any Tennessee county when prescribed by the patient's physician.
- AxelaCare Health Solution's Specialty Pharmacy and Sterile Compounding programs in Kansas are licensed by the Kansas Board of Pharmacy with an expiration date of June 30, 2017.

Certification

- The applicant will not seek certification by Medicare and Medicaid/TennCare.

Accreditation

- The applicant's pharmacy operation is currently accredited by The Joint Commission with an effective date of April 18, 2015 valid for up to 36 months.
- AxelaCare's Specialty Pharmacy Program is accredited by URAC (Utilization Review Accreditation Program).

CONTRIBUTION TO THE ORDERLY DEVLOPMENT OF HEALTHCARE

Agreements

- The applicant expects to develop referral and working relationships with hospitals, specialty medical practices, and home health agencies in the Memphis and Jackson areas.

Impact on Existing Providers

- The applicant surveyed 40 home health agencies and discovered only one respondent (Coram/CVS Specialty Infusion Service) was currently prepared region-wide to provide timely IVIG (intravenous immune globulin) home care that include a first dose session.
- Many home health agencies are reluctant to provide home infusion services. The highly specialized IVIG service is challenging and unprofitable for almost all home health agencies in West Tennessee.

Staffing

- The applicant's direct patient care staffing for the home health agency is projected as 2.5 FTE Certified Infusion Registered Nurses (RN) in Year One increasing to 3.5 FTEs in Year 2.

Corporate documentation and office lease information are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in two years.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other pending applications, Letters of Intent, denied applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

Letters of Intent

Premier Health Care, LLC, CN1608-027, filed a letter of intent on August 1, 2016 for the establishment of a home care organization and the initiation of home health services. The proposed service area will consist of Fayette, Haywood, Madison, and Tipton Counties. The principal office will be located at 2855 Stage Village Cove, Suite #5, Bartlett (Shelby County), TN. The estimated project cost is **$50,000**.

Pending Applications:

VIP Home Nursing and Rehabilitation Services d/b/a CareAll Home Care Services, CN1608-028, has a pending application scheduled to be heard at the October 26, 2016 agency meeting. The application is for the addition of six counties (Maury, Giles, Lawrence, Wayne, Lewis, and Hickman) to the existing 22 county licensed service area of VIP Home Nursing and Rehabilitation Services d/b/a CareAll Home Care Services located at 4015 Travis Drive, Suite 102, Nashville, TN 37211. The estimated project cost is **$21,000**.

MaxLife at Home of Tennessee d/b/a CareAll Home Care Services, CN1608-029, has a pending application scheduled to be heard at the October 26, 2016 agency meeting. The application is for the relocation of the applicant's principal office from 900 Nashville Highway, Columbia (Maury County) to 4015 Travis Drive, Suite 102, Nashville, TN 37211. The relocation will occur with the surrender of Maury, Giles, Lawrence, Lewis, Wayne, and Hickman Counties from the licensed service area and the transfer of these six counties to the applicant's sister Agency of VIP Home Nursing and Rehabilitation Services, LLC dba CareAll. The remaining service area will consist of Cheatham, Davidson, Rutherford, Williamson, Robertson, Sumner, Hardin, McNairy, Decatur, Lewis, Perry, Hickman, and Humphreys. The estimated project cost is **$67,054.88**.

Denied Applications:

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby,

Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was **$177,800.00**. *Reasons for Denial: 1) Need-There has not been a supported need in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility-The project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.*

Outstanding Certificates of Need:

Alere Women's & Children's Health, CN1512-056A, has an outstanding Certificate of Need that will expire on May 1, 2018. The application was approved at March 23, 2016 Agency meeting for the addition of 16 counties, including, Benton, Carroll, Chester, Crockett, Decatur, Dyer, Gibson, Hardin, Henderson, Henry, Lake, McNairy, Obion, Perry, Wayne, and Weakley Counties to the existing 7-county service area of Alere Women's and Children's Health, a home health organization licensed by the Tennessee Department of Health whose parent office is located at 3175 Lenox Park Blvd, Suite 400, Memphis (Shelby County), TN, 38115. **The estimated project cost is $79,000.** *Project Status: An update received September 28, 2016 reported the project is completed and patients are being served. A final project report is pending.*

Implanted Pump Management, CN1406-027A, has an outstanding Certificate of Need that will expire on August 1, 2017. The application was approved at the June 24, 2015 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to intrathecal pump services. The parent office will be located at 200 Prosperity Place #102, Knoxville (Knox County), TN 37932. There are no branch offices proposed for this project. The service area includes all 95 counties in Tennessee. The estimated project cost is **$8,100.00.** *Project Status: A project status report dated September 29, 2016 states the Agency is licensed and receiving patients. A final project report is pending.*

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services CN1406-018A has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office

will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is **$98,000.00.** *Project Status Update: As of October 7, 2016 the applicant is licensed. An Annual Project Report is pending.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, HEALTH CARE THAT MEETS APPROPRIATE QUALITY STANDARDS, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME
10/7/2016

LETTER OF INTENT

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before June 10, 2016, for one day, in the following newspapers:

(a) The *Commercial Appeal*, which is a newspaper of general circulation in *Crockett, Fayette, Hardeman, Hardin, Haywood, Lake, Lauderdale, McNairy, Obion, Shelby, Tipton* and *Weakley Counties*;

(b) The *Jackson Sun*, which is a newspaper of general circulation in *Carroll, Chester, Decatur, Gibson, Henderson* and *Madison Counties*;

(c) The *Paris Post-Intelligencer*, which is a newspaper of general circulation in *Benton* and *Henry Counties*; and

(d) The *Dyersburg State Gazette*, which is a newspaper of general circulation in *Dyer County*.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

John Wellborn 6-9-16 jwdsg@comcast.net

(Signature) (Date) (E-mail Address)

COPY

AXELACARE HEALTH SOLUTIONS

CN1606-022

AXELACARE HEALTH SOLUTIONS

CERTIFICATE OF NEED APPLICATION TO ESTABLISH A HOME HEALTH AGENCY SERVING WEST TENNESSEE

LIMITED TO HOME INFUSION OF IMMUNE GLOBULIN MEDICATIONS

Submitted June 2016

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

PART A

1. *Name of Facility, Agency, or Institution*

AxelaCare Health Solutions		
Name		
5100 Poplar Avenue, 27th Floor, Suite 2739		Shelby
Street or Route		*County*
Memphis	TN	38137
City	*State*	*Zip Code*

2. *Contact Person Available for Responses to Questions*

John Wellborn		Consultant	
Name		*Title*	
Development Support Group		jwdsg@comcast.net	
Company Name		*E-Mail Address*	
4219 Hillsboro Road, Suite 210	Nashville	TN	37215
Street or Route	*City*	*State*	*Zip Code*
CON Consultant	615-665-2022	615-665-2042	
Association With Owner	*Phone Number*	*Fax Number*	

3. *Owner of the Facility, Agency, or Institution*

AxelaCare Health Solutions, LLC		913-747-3717
Name		*Phone Number*
c/o Office of General Counsel, AxelaCare, 15529 College Blvd		Johnson (KS)
Street or Route		*County*
Lenexa	Kansas	66219
City	*State*	*Zip Code*

4. *Type of Ownership or Control (Check One)*

A. Sole Proprietorship		F. Government (State of TN or Political Subdivision)	
B. Partnership		G. Joint Venture	
C. Limited Partnership		H. Limited Liability Company	x
D. Corporation (For-Profit)		I. Other (Specify):	
E. Corporation (Not-for-Profit)			

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS

5. *Name of Management/Operating Entity (If Applicable)* *NA*

Name

Street or Route *County*

City *State* *Zip Code*

6. *Legal Interest in the Site of the Institution (Check One)*

A. Ownership		D. Option to Lease	
B. Option to Purchase		E. Other (Specify):	
C. Lease of __1__ Years, renewable			

7. *Type of Institution (Check as appropriate—more than one may apply)*

A. Hospital (Specify): General		I. Nursing Home	
B. Ambulatory Surgical Treatment Center (ASTC) Multi-Specialty		J. Outpatient Diagnostic Center	
C. ASTC, Single Specialty		K. Recuperation Center	
D. Home Health Agency	x	L. Rehabilitation Center	
E. Hospice		M. Residential Hospice	
F. Mental Health Hospital		N. Non-Residential Methadone	
G. Mental Health Residential Faclity		O. Birthing Center	
H. Mental Retardation Institutional Habilitation Facility (ICF/MR)		P. Other Outpatient Facility (Specify):	
		Q. Other (Specify):	

8. *Purpose of Review (Check as appropriate—more than one may apply*

A. New Institution	x	G. Change in Bed Complement Please underline the type of Change: Increase, Decrease, Designation, Distribution, Conversion, Relocation	
B. Replacement/Existing Facility		H. Change of Location	
C. Modification/Existing Facility		I. Other (Specify):	
D. Initiation of Health Care Service as defined in TCA Sec 68-11-1607(4) (Specify) home health IgG	x		
E. Discontinuance of OB Service			
F. Acquisition of Equipment			

9. *Bed Complement Data* — *Not Applicable*

(Please indicate current and proposed distribution and certification of facility beds.)

	Current Licensed Beds	**CON approved beds (not in service)**	**Staffed Beds**	**Beds Proposed (Change)**	**TOTAL Beds at Completion**
A. Medical					
B. Surgical					
C. Long Term Care Hosp.					
D. Obstetrical					
E. ICU/CCU					
F. Neonatal					
G. Pediatric					
H. Adult Psychiatric					
I. Geriatric Psychiatric					
J. Child/Adolesc. Psych.					
K. Rehabilitation					
L. Nursing Facility (non-Medicaid certified)					
M. Nursing Facility Lev. 1 (Medicaid only)					
N. Nursing Facility Lev. 2 (Medicare only)					
O Nursing Facility Lev. 2 (dually certified for Medicare & Medicaid)					
P. ICF/MR					
Q. Adult Chemical Dependency					
R. Child/Adolescent Chemical Dependency					
S. Swing Beds					
T. Mental Health Residential Treatment					
U. Residential Hospice					
TOTAL					

10. Medicare Provider Number: **Certification Type:**	Not applicable
11. Medicaid Provider Number: **Certification Type:**	Not applicable

12. & 13. See page 4

A.12. IF THIS IS A NEW FACILITY, WILL CERTIFICATION BE SOUGHT FOR MEDICARE AND/OR MEDICAID?

This is a proposed new home health agency limited to providing home infusion services and products to non-Medicare, non-TennCare, and typically non-homebound patients who need immune globulin medications.

The patients whom AxelaCare Health Solutions, LLC ("AxelaCare") seeks authorization to serve do not meet Medicare Conditions of Participation (""COP"), except in rare instances. As one example, Medicare does not reimburse for home infusion for patients that are not "homebound"--and almost none of AxelaCare's patients will be classified as homebound. Due to TennCare's policy of limiting TennCare participation to providers with a Medicare provider number, AxelaCare is not allowed to contract with TennCare.

AxelaCare will continue to contract with existing home health agencies to serve Medicare- and TennCare-insured patients who are referred to AxelaCare, -- *i.e.,* patients for whom the referring physician prescribes an AxelaCare pharmaceutical product and requests AxelaCare to arrange to administer the patient's infusion. The only exceptions will be Medicare enrollees who, in addition to their Medicare insurance option, also have alternate coverage under a privately purchased "Medicare replacement plan". These patients will be few in number and will be accounted for as commercially insured patients, consistent with the source of reimbursement.

A.13. IDENTIFY ALL TENNCARE MANAGED CARE ORGANIZATIONS / BEHAVIORAL HEALTH ORGANIZATIONS (MCO'S/BHO'S) OPERATING IN THE PROPOSED SERVICE AREA. WILL THIS PROJECT INVOLVE THE TREATMENT OF TENNCARE PARTICIPANTS? *No.* IF THE RESPONSE TO THIS ITEM IS YES, PLEASE IDENTIFY ALL MCO'S WITH WHICH THE APPLICANT HAS CONTRACTED OR PLANS TO CONTRACT.
DISCUSS ANY OUT-OF-NETWORK RELATIONSHIPS IN PLACE WITH MCO'S/BHO'S IN THE AREA.

The proposed agency is not eligible to seek contracts with TennCare managed care organizations (MCO's) operating in its service area because the agency cannot participate in Medicare.

SECTION B: PROJECT DESCRIPTION

B.I. PROVIDE A BRIEF EXECUTIVE SUMMARY OF THE PROJECT NOT TO EXCEED TWO PAGES. TOPICS TO BE INCLUDED IN THE EXECUTIVE SUMMARY ARE A BRIEF DESCRIPTION OF PROPOSED SERVICES AND EQUIPMENT, OWNERSHIP STRUCTURE, SERVICE AREA, NEED, EXISTING RESOURCES, PROJECT COST, FUNDING, FINANCIAL FEASIBILITY AND STAFFING.

Proposed Services and Equipment

- The applicant seeks licensure as a home health agency limited to home infusions of AxelaCare immune globulin products (and nursing services necessary for those products), to serve a small number of privately insured West Tennessee patients who are immune-compromised, and whose physicians have prescribed use of AxelaCare specialty medications.

- Approval is requested for the entire West Tennessee service area, starting in CY 2017.

- The new agency will have its principal office in Memphis/Shelby County. Field nursing staff will be based in Memphis and also in one of more cities that are closer to the easternmost counties in the service area.

- The patients served by the project will not be eligible for Medicare or TennCare reimbursement for home care nursing, under existing reimbursement rules.

Ownership Structure

- Attachment A.4 contains more details, an organization chart, and information on the Tennessee facilities owned by this facility's parent organization.

Service Area

- The proposed service area consists of 21 West Tennessee counties -- all 20 counties that are west of the Tennessee River plus Hardin County. They are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

Need

- Referring physicians who prescribe specialty pharmaceuticals provided by AxelaCare face serious delays in finding agencies who will administer specialty infusion care in a timely and optimal manner. The physicians and their patients need a provider who can (a) start infusions in the patient's home without delay; (b) provide highly skilled nurses specializing in specialty infusion; (c) provide superior communication to the physician

and pharmacist working with the patient; and (d) serve their West Tennessee patients who live in remote rural areas. All four criteria must be met for optimal care of this unique patient population. Yet, out of the 52 currently existing home health agencies in the service area, the applicant knows of only one (1) agency that meet all four criteria. Two (2) other agencies indicate that they have the capability to provide this type of care, but their service areas include only a few urbanized counties in the service area. Providing intravenous immune globulin infusions in the home is a specialty service that almost no existing agencies are staffed to provide.

• Delays in starting home care infusions immediately upon the physician's orders forces patients either to incur the burden of turning to a freestanding or outpatient infusion center, or even on occasion to remain in a hospital extra days. Extra time in a hospital drives up costs. Use of facilities outside the patient home requires frequent and burdensome commuting on multiple days. Such commuting imposes on these immune-compromised patients a risk of contracting opportunistic infections through exposure to other persons. Commuting is also less convenient and typically more expensive than obtaining infusion care in one's home.

• At an annual caseload of only 65 patients in Year Two, this project can greatly improve care for immune-compromised patients with very special needs without having any significant adverse impact on existing home health providers, who collectively served more than 39,000 patients in 2015. In fact, given that existing agencies will probably increase their caseloads by more than 3,000 patients by Year One of this project, it is likely that AxelaCare's entry will not have even a noticeable impact on existing agencies.

Existing Resources

• Publicly available data do not provide patient care data specific to patients receiving immune globulin infusions. The applicant knows of 52 home health agencies serving the area, but has not been able to identify more than one that meets all four of the criteria for optimal care that are stated above

Project Cost, Funding, and Financial Feasibility

• The estimated $69,628 cost of the project is very minimal. Excluding lease payments, the capital cost is only $58,000. This will be funded entirely by the applicant's parent company.

• The AxelaCare home health nursing service that is proposed in this application will operate at a financial loss. But AxelaCare's Kansas-based specialty pharmacy that supports the nursing service is already licensed and operating throughout Tennessee; and it will be profitable enough to absorb those losses. There will be a positive margin when those two components of care delivery are viewed in combination.

Staffing

• The project requires only 6 FTE's of skilled care nurses, all of whom are RN's.

B.II. PROVIDE A DETAILED NARRATIVE OF THE PROJECT BY ADDRESSING THE FOLLOWING ITEMS AS THEY RELATE TO THE PROPOSAL.

B.II.A. DESCRIBE THE CONSTRUCTION, MODIFICATION AND/OR RENOVATION OF THE FACILITY (EXCLUSIVE OF MAJOR MEDICAL EQUIPMENT COVERED BY T.C.A. 68-11-1601 *et seq.)* INCLUDING SQUARE FOOTAGE, MAJOR OPERATIONAL AREAS, ROOM CONFIGURATION, ETC.

This project for a new home health agency will require establishment of a home office in Memphis/Shelby County.

The home office will be established in leased space -- a one-room, 149-SF office in the Executive Suite (Suite 2700) on the 27th floor of the Clark Tower, a commercial office building located at 5100 Poplar Avenue, Memphis, Shelby County, Tennessee 38137. The home office will be used only by the agency's administrative staff, which consists of one person. It requires no renovation or installation of patient care equipment. Minimal furnishings will be required. No clinical equipment or supplies will be stored in this space. As done by AxelaCare in other States, all patient pharmaceuticals, supplies and equipment needed for home infusion of immune globulin medications will be direct-shipped from Kansas to the patients' homes.

APPLICANTS WITH HOSPITAL PROJECTS (CONSTRUCTION COST IN EXCESS OF $5 MILLION) AND OTHER FACILITY PROJECTS (CONSTRUCTION COST IN EXCESS OF $2 MILLION) SHOULD COMPLETE THE SQUARE FOOTAGE AND COSTS PER SQUARE FOOTAGE CHART.....

Not applicable.

PLEASE ALSO DISCUSS AND JUSTIFY THE COST PER SQUARE FOOT FOR THIS PROJECT.

The home office will be an administrative space only. No clinical services will be provided in that space. The applicant is leasing finished space at market rates. The project requires no remodeling, renovation or new construction.

IF THE PROJECT INVOLVES NONE OF THE ABOVE, DESCRIBE THE DEVELOPMENT OF THE PROPOSAL.

A. The Applicant

AxelaCare Health Solutions, LLC ("AxelaCare") is the Certificate of Need applicant. The applicant LLC is wholly owned by UnitedHealth Group Incorporated through seven wholly owned intermediary corporations and LLC's, which are shown in the organization chart in Attachment One of the application.

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction which it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications, AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients' homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient's infusion.

Five of those states -- Illinois, Indiana, Texas, Virginia and New Jersey -- require licensure to provide home care, as does Tennessee. This project seeks Tennessee licensure to establish an integrated AxelaCare home infusion program across all of West Tennessee for patients utilizing AxelaCare infusion medications for immune globulin. This CON application will be followed by two more CON applications requesting similar

authorization for Middle and East Tennessee with the objective of becoming one of the few statewide providers of home infusion of immune globulin medications.

B. The Project

1. Limited Scope of Services

"Specialty home infusion" is the process of providing very specialized medicines intravenously in a patient's home, with the presence and support of a skilled registered nurse who works under the direction of the patient's referring physician. It is a type of home health care that very few Tennessee home health agencies are staffed or willing to provide.

AxelaCare is requesting approval to become licensed as a home health agency based in Memphis and authorized to provide direct services and product for specialty home infusion of ***its immune globulin medications only***. These services would be limited to adult and pediatric patients in 21 contiguous West Tennessee counties, using AxelaCare's own skilled registered nursing staff. The service will provide infusion of Immune Globulin either directly into the vein or through a subcutaneous (under the skin) site.

The applicant is not requesting authorization for infusion of other medications. This limitation to only one narrow type of specialty infusion (immune globulin products) distinguishes this project from all other home health agencies in the project service area. In this application, the service is abbreviated as "IVIG" (intravenous immune globulin).

2. Physical Facilities Required for the Services

Licensure of the project will require AxelaCare to establish a home office in the proposed service area. The site selected for the home office is Suite 2700 on the 27th floor of the "Clark Tower" building at 5100 Poplar Avenue, Memphis, Shelby County, Tennessee 38137. The leased space will consist of one 149-SF office in an Executive Suite on that floor. The office will be used only by the agency's administrative staff,

which consists of one person. It requires no renovation or installation of patient care equipment. Consistent with AxelaCare's operations in other states, minimal furnishings will be required, and no clinical equipment or supplies will be stored in this space. The pharmaceuticals, supplies, and equipment needed for home infusion of immune globulin medications will be direct-shipped to the patients' homes, where AlexaCare registered nurses will administer and manage the infusion process in consultation with the AlexaCare pharmacist and the patient's physician.

3. Counties to be Served

The proposed service area consists of 21 Tennessee counties. They are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties. Please see the Attachments for a map of this area and its location within the State of Tennessee.

4. Staffing of the Services

The applicant projects employment of 6.0 FTE's of clinical and administrative staff in Year Two. That number includes 3.3 FTE's of CRNI's (Certified Infusion RN's) who will provide specialized infusion home care.

The RN's will be specially trained in starting and managing home infusions. They will be trained thoroughly in the AxelaCare infusion program and in the use of Axela's CareExchange software--which is an iPad platform for documenting patient dosages and responses. CareExchange permits real-time communication with the team pharmacist and the referring physician while the nurse is on-site. Nurses employed by AxelaCare for this service will be asked to have, or to obtain within one year of employment, the Certified Registered Nurse Infusion (CRNI) designation which denotes special competence in managing infusions.

The AxelaCare staff's specialization in home infusion care of the immune globulin recipient, and the CRNI designation that AxelaCare nurses will attain in

Tennessee are another distinction between this service and almost all other home health care organizations operating in West Tennessee.

5. Schedule for Implementing the Services

If granted final CON approval on or before October 2016, Axelacare projects occupancy of its office, State licensure and initiation of patient care by the end of CY2016. The first full year of operation is projected to be CY2017.

6. Costs and Funding of the Project

There are very few costs associated with the project, which requires only leasing and furnishing one small administrative/management home office in Shelby County. The total cost for CON purposes, which includes the value of the leased space, is estimated at $69,628. Of that, $58,000 is the actual capital cost of implementing the project. The balance of $11,628 is the lease outlay during the first term of the lease, which is required to be included in calculating project costs for CON review purposes. All required capital costs will be provided by UnitedHealth Group, the applicant's parent company in the form of a cash transfer.

C. Patient Needs Addressed By the Project

Immune Globulin is a medicine that contains antibodies, which are tiny proteins that patrol the blood stream to alert the body to germs, which the body then can destroy through complex "immune system" responses.

Specialists in many areas of medicine use immune globulin infusions (IVIG) when other therapies have failed. Referring medical specialties most likely to utilize this AxelaCare program will include neurologists, immunologists, oncologists, and dermatologists. They prescribe immune globulin therapy to treat patients with challenging immune system disorders of many kinds, including the following (several of which are briefly described near the end of this response).

- Peripheral Neuropathy (PN)
- Small Fiber Neuropathy (SFN)
- Primary Immunodeficiency Disease (PIDD)
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Guillain-Barre Syndrome (GBS)
- Multifocal Motor Neuropathy (MMN)
- Myasthenia Gravis (MG)
- Multiple Sclerosis (MS)
- Pemphigoid / Pemphigus
- Common Variable Immunodeficiency Disease (CVID)
- Chronic Granulomatous Disease (CGD)
- Hyper IgM Syndrome
- Selective IgA Deficiency (SIgAD)
- Severe Combined Immunodeficiency Disease (SCID)
- Wiskott-Aldrich Syndrome
- X-linked Agammaglobulinemia
- Auto-immune Encephalopathy (AE)
- Dermatomyositis
- Idiopathic Thrombocytopenia Purpura (ITP)
- Lambert-Eaton Myasthenic Syndrome (LEMS)
- Mononeuritis Multiplex
- Polymyositis
- Transplant-related Conditions
- Stiff-person Syndrome (SPS)

The patients who will be served by this project are often among the most challenged of home health patients. Their care requires very sophisticated management by their physicians and the skilled care nurses who carry out prescribed home infusions.

Very few home health agencies are willing and able to offer ready availability of the specialized skilled nursing staff that is needed when providing IVIG infusions at home. Optimal nursing care for IVIG infusion requires significant nursing experience and training. It requires the nurse to spend long hours with the patient over a prolonged treatment period, during which significant monitoring of patient responses takes place. In the AxelaCare service model, nurses also record patient data continuously for the referring physician to review during and after the course of the dosing -- and for post-care research, as explained below.

D. AxelaCare's Program for Delivery of Home Infusion Care for IVIG Patients

AxelaCare is dedicated solely to comprehensive excellence in specialty home infusion care. Its highly trained and experienced clinical staff are its own employees. Its internal Quality Improvement program is among the most robust in the industry. And, most notably, the technology it uses in the patient's home during the infusion treatment is continuously gathering clinical data that is made available not only to the patient's physician, but also to medical researchers (with properly obtained consent) -- thus advancing medical knowledge in a complex and evolving area of medicine. AxelaCare's sequence of services to its West Tennessee IVIG patients will be as follows:

1. Patient and Physician Contacts

AxelaCare has relationships with medical specialists in the service area and will work with them to ensure that patient referral processes are straightforward and efficient. When a referral is made, the AxelaCare staff will secure required information and paperwork from the physician's office and will send it to an AxelaCare Pharmacy. The Pharmacy will (a) assign a Pharmacist with 24/7 availability to the patient; (b) prepare the prescribed pharmaceuticals; and (c) direct-ship them in the correct dosages to the patient's home for infusion. An AxelaCare specialty home infusion nurse will be assigned to provide care to the West Tennessee patient.

2. Comprehensive Assistance to the Patient Prior to Infusion

After contacting the referred patient, AxelaCare's Care Team will simplify arrangements for the patient's insurance coverage, evaluating all benefit sources and potential coverage, obtaining letters of medical necessity, securing coverage for patients previously denied, educating the patient on available benefits and the patient's projected costs, coordinating with the physician's office for timely approvals and prior authorizations and coordinating direct billing to insurance and other payment sources.

3. The Initial Home Visit

An initial home visit is scheduled so that the skilled care infusion nurse can become personally acquainted with the patient and his/her home environment, discuss the infusion process, answer patient questions, establish a schedule of visits, and obtain required patient consent to share with the patient's physician and with AxelaCare's research center a set of clinical data and information to be obtained during infusion sessions.

4. Preparation for Infusion or "Dosing"

Before home infusion begins, many patients need oral or venous hydration and/or premedication to lower the risks associated with infusion, which can include headaches and blood pressure changes. In infusion medicine, a "dose" is not a "visit" or "hours" as in most home health care. A dose is a prescribed amount of medication to be administered in a single "dosing cycle". A dosing cycle can take from ***one to five consecutive days***, depending on the amount to be infused and on the infusion rate that the patient can tolerate without having negative reactions. Dosing cycles may be required at weekly intervals.

5. Care During the Infusion Sessions

A nursing visit in a dosing cycle can be from 2 to 10 hours daily in duration, depending on the prescription, the dose amount, dose rate and patient reactions to the infusion. Before, during, and after infusion, the AxelaCare nurse follows detailed protocols, that include periodically taking vital signs, taking spirometry readings, discussing the patient's bodily responses to the infusion, requesting patient performance of simple physical tests such as grip strength measurement and rising from a chair to walk across the room.

6. CareExchange Technology

One of the distinguishing advantages of AxelaCare "bedside" services is CareExchange -- a unique and proprietary technology tool developed by AxelaCare in

2012. Continuously during every dosing day, the nurse gathers and enters all clinical data and patient descriptions of pain, fatigue, etc. into an iPad fitted with CareExchange software. CareExchange organizes this information into clear and usable reports that are then transmitted over secure electronic channels to the patient's AxelaCare pharmacist and to the patient's physician.

With this "real-time" data, both the pharmacist and the referring physician specialist can more quickly evaluate patient reactions to the medication and can direct appropriate adjustments such as variations in the dosing rate or dosing amount, as indicated by digitally documented patient reactions. In addition, the infusion nurse can identify and discuss issues with the AxelaCare pharmacist during, as well as after, infusion (the pharmacist is available 24/7), and the pharmacist and nurse can telephonically alert the physician to patient response issues and can discuss modifications of the treatment.

CareExchange's capturing and analysis of patient response data during the dosing cycle, and its rapid communication to the treatment team, helps both the patient and the referring physician. From the ***patient's*** perspective, it ensures that patients are receiving optimal therapy for maximum effectiveness of the infusion medication. The technology tracks patient progress and changes in the patient's condition. It establishes baseline and trending information to compare those changes. From the ***physician's*** perspective, it provides real-time data between patient office visits, to help manage the patient's condition; it allows rapid adjustment of the prescribed therapy to find the most effective dose; and it gives a better understanding of how the therapy is working and how it might work for other patients with similar conditions.

7. Use of Patient Data for Research

The AxelaCare program does not end with completion of the dosing. With patient consent, the clinical data gathered by CareExchange is compiled centrally at AxelaCare and is used to advance medical knowledge in this complex and evolving area of care. It is used in clinical trials with independent researchers. It is used in research published in clinical journals and in seminars presented at professional gatherings.

AxelaCare is currently working on clinical trials and journal publications with medical staff at Northwestern University, the University of Minnesota, the University of Virginia, Columbia University Medical Center, the University of Kansas and the "Neurology at John's Creek" practice group in Georgia. AxelaCare's ongoing contributions to clinical research is one of the special benefits of permitting AxelaCare to expand into Tennessee. Its program will contribute to the orderly development of more effective healthcare services not only in Tennessee, but also throughout the field of infusion medicine.

8. Examples of Disorders That Often Require Immune Globulin (IVIG) Therapy

• Peripheral neuropathy--This is a disorder of the peripheral nervous system (the system connecting the brain and spine to limbs, muscles, skin, and internal organs). It affects approximately 60% of all diabetics. Symptoms often start in the fingers and toes, and can include muscle weakness and even paralysis if motor nerves are affected. Other symptoms may include burning pain in the hands and feet; sharp electric shock pains; problems in gripping; sensitivity to pain, touch and temperature; bowel and bladder dysfunction; sweating; and abnormal blood pressure.

• Small fiber neuropathy--Most prevalent among the elderly and many diabetics (50% prevalence), this peripheral nervous system disorder most often starts with numbness in the toes and a burning sensation in the feet. It is often worse at night, creating sleep difficulties. It may develop into pain and burning, or loss of feeling, or "pins and needles" feelings or numbness in hands and feet. It may cause cramping, fatigue, inability to sweat, dry eyes, dizziness, difficulty in breathing, difficulty with elimination and increased heart rate.

• Primary immunodeficiency (PIDD)--There are over 200 types of PIDD, and they are inherited disorders all involving a shortage of antibodies that result in more frequent sicknesses and decreased ability to get better from an infection. Maladies typically experienced include frequent pneumonia and bronchitis, ear and sinus infections, sore throats, coughs, colds and flu, fungal infections, rare viruses and slowness of wound healing. In children, PIDD can also result in slow growth and below-normal weight.

• Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)--This disorder is very difficult to correctly diagnose. It afflicts men at twice the rate of women. It is a chronic disorder requiring long-term treatment. Symptoms can be mild or can progress to the point where they impair motor skills. Symptoms may include weakness of loss of feeling in extremities; difficulty of movement in climbing stairs or standing on tip-toe; weakness of hands; loss of balance; and sensations of numbness, tingling, prickling or burning.

• Guillain-Barre Syndrome (GBS)--This is rare illness of unknown origin. Patient symptoms typically begin as weakness or tingling in the feet and legs, spreading in an upward direction through arms, legs and torso. Extreme cases can result in paralysis. Potential symptoms include unsteadiness and clumsiness in walking; muscle contraction and blurred vision; back pain; difficulty in eye movement, facial movement, speaking, chewing or swallowing; and breathing difficulty when diaphragm and chest areas are affected.

• Multifocal Motor Neuropathy (MMN)--This rare muscle disorder causes increasing muscle weakness over time. It is often misdiagnosed as ALS or Lou Gehrig's Disease. Its symptoms include muscle cramps, wasting and shrinkage; involuntary twitching and spasms; numbness and tingling; difficulty getting up from a seated position and in climbing steps.

• Myasthenia Gravis (MG)-- This disorder is rare, most often affecting men over 60 years of age and women under 40. Persons with this condition may have difficulty in breathing, chewing, swallowing, climbing steps, lifting and gripping objects, speaking and rising from a seated position. They may often suffer from weak arm and chest muscles, drooping head or eyes, fatigue, double vision and balance issues.

• Multiple Sclerosis (MS)--Most commonly diagnosed between the ages of 20 and 40, MS symptoms vary from mild to severe. If is difficult to predict the onset or affects of patients; symptoms are often triggered by events such as fevers, hot baths, sun exposure or stress. Symptoms include blurred or double vision or vision loss; distorted perception of red/green colors; tremors; pain; "pins and needles" feelings in spots; and difficulty walking or getting up from a seated position. Other symptoms may include arm and leg weakness; coordination and balance problems; spasms; dizziness; loss of sensation;

hearing loss; issues of bowel and bladder control; and fatigue and depression. Patients may have periods of relief of symptoms; or the symptoms may get progressively worse with few or no remission periods.

B.II.B. IDENTIFY THE NUMBER AND TYPE OF BEDS INCREASED, DECREASED, CONVERTED, RELOCATED, DESIGNATED, AND/OR REDISTRIBUTED BY THIS APPLICATION. DESCRIBE THE REASONS FOR CHANGE IN BED ALLOCATIONS AND DESCRIBE THE IMPACT THE BED CHANGE WILL HAVE ON EXISTING SERVICES.

Not applicable.

B.II.C. AS THE APPLICANT, DESCRIBE YOUR NEED TO PROVIDE THE FOLLOWING HEALTH CARE SERVICES (IF APPLICABLE TO THIS APPLICATION):

1. **ADULT PSYCHIATRIC SERVICES**
2. **ALCOHOL AND DRUG TREATMENT ADOLESCENTS >28 DAYS**
3. **BIRTHING CENTER**
4. **BURN UNITS**
5. **CARDIAC CATHETERIZATION SERVICES**
6. **CHILD AND ADOLESCENT PSYCHIATRIC SERVICES**
7. **EXTRACORPOREAL LITHOTRIPSY**
8. **HOME HEALTH SERVICES.....**

A. Demand for Home Infusion Services Is Increasing Nationally

Although the targeted under-65 populations are slowly increasing in West Tennessee, the uses and demand for intravenous immune globulin medications is likely to increase rapidly in that region. This is consistent with national trends.

Immune globulin infusion (IVIG) is used to treat a wide range of disorders. While the most common use of IVIG therapy is in treating primary immune deficiencies, its efficacy in numerous other disorders is well-documented. Off-label prescription of these successful medications far exceeds the volumes for FDA-approved usages and off-label research is burgeoning. It is estimated that for every USFDA- approved indication, there are more than ten non-FDA-approved indications. Current research is even exploring IVIG's potential for reducing development of Alzheimer's and increasing live births for women with secondary recurrent miscarriage issues. (Rhodes and McFalls; On- and Off-Label Uses and Clinical Trials of IG).

According to an August 2015 editorial in Frontiers in Immunology, "There has been a steady increase in demand for immune globulin medications over the past 20 years, in in research into the mechanisms through which it has been found to help with certain conditions... (This is) an exciting and fruitful area of clinical research, and well-suited to contribute to the ongoing evolution in medicine toward more individualized and patient-centric paradigms."

Although Medicare has not allowed most of its enrollees to receive home infusion nursing services, Congress recently asked the General Accounting Office ("GAO"") to look into the need to revisit that position. GAO Report GAO-10-426 identified that commercial insurers have long covered home infusion therapy comprehensively and have had good experience with its cost-benefit impact and quality of care. GAO recommended that HHS study this to inform Congress about potential program costs, savings and other issues that would be associated with comprehensive Medicare benefits for home infusion therapy. HHS now has such a study underway. Medicare has preliminarily reported that "there was approximately a 60% growth rate in Medicare beneficiaries...receiving immune globulin treatment over the past 5 years...", and that infusions were given primarily in hospitals, outpatient departments, infusion suites and physician offices. There is already Congressional support for draft legislation authorizing Medicare to cover infusions in the more convenient and lower-cost home setting when physicians and patients prefer it.

B. Many Home Health Agencies are Reluctant to Provide Home Infusion Services

There are 52 home health agencies licensed to serve one or more of the counties in the proposed West Tennessee service area. But this highly specialized IVIG service is very challenging and unprofitable for almost all of them, so few agencies offer it. There are several reasons why home health agencies ("HHA's") providing routine home health services seldom offer IVIG.

(1) There are *risks of adverse patient reactions*, especially to the first infusion. These risks are not acceptable to most agencies. Less complex and more predictable patients are sought by most agencies.

(2) The infusions also require a *highly skilled infusion registered nurse*. Most agencies do not have such staff available at the time that it is needed and do not provide staff training required to create a high level of competency in home infusion care.

(3) IVIG infusions require the home health nurse to be present and to be highly observant and active in the recording of patient clinical information for periods of time *2-10 hours per session*. Few home health agencies want to offer a service that ties up the nurse for

more than two hours. Many nurses do not want to spend such long hours in this demanding type of home care.

(4) The best home infusion care for complex patients enables immediate nursing consultation with the referring physician office and/or with the assigned pharmacist, during the infusion session (not just afterwards). Best practice in this area now requires new technologies to empower the home infusion nurse to do this. To respond to this need, AxelaCare has developed its own iPad-based CareExchange technology, which allows its nurses to optimize the accuracy, ease and speed of gathering information and communicating it to the physician and team pharmacist -- both during and after infusion sessions, as appropriate. Home health agencies providing only general home health care do not typically invest in such technology and training for the benefit of such a small patient population as the IVIG patient.

C. The Shortage of Home Infusion Providers in West Tennessee

Because of the limitations described above, almost none of the service area's numerous home health agencies meet area needs for home infusion of patients requiring immune globulin.

The applicant conducted a telephone survey of almost all licensed area home health agencies to determine if they were currently staffed or had a subcontract in place to provide immune globulin home infusion without delay. (Five area agencies were not contacted because they do not serve the Memphis area and also serve fewer than three rural counties. One was not contacted because it serves only pregnant women and does not infuse immune globulin. Three of five area Amedysis agencies were contacted and they were assumed to be representative of the other two agencies.) The results are shown below in Table One below.

Out of forty-six listed agencies, forty provided information. Only *one* respondent was currently prepared *region-wide* to provide timely IVIG home care that would include the most costly, risky, and labor-intensive first dosing session. Only *two* other agencies were similarly prepared; but they are licensed to serve only six urban counties in this region. They cannot meet patient needs in fifteen more rural counties.

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

Table One: AxelaCare Telephone Survey of Home Health Agencies in Project Service Area

Health Statistics ID	Agency County	Agency	Are you staffed at this time, or do you have a staffing subcontract in place, to provide IV infusion of immune globulin (IVIG) upon request?		
			NO	YES, WITH OWN STAFF	YES, WITH SUBCONTRACTED STAFF
79456	Shelby	Accredo Health Group, Inc.	X		
79146	Shelby	Amedisys Home Care	X*		
33103	Hamilton	Amedisys Home Health	X*		
57075	Madison	Amedisys Home Health Care	X		
79246	Shelby	Amedisys Home Health Care	X		
79386	Shelby	Amedisys Tennessee, LLC (D/B/A Amedisys HH)	X		
79256	Shelby	Americare Home Health Agency, Inc	X		
09065	Carroll	Baptist Memorial Home Care & Hospice	X		
79276	Shelby	Baptist Trinity Home Care	X		
79446	Shelby	Baptist Trinity Home Care - Private Pay	X		
79546	Shelby	Best Nurses, Inc.	X		
38015	Haywood	Careall Homecare Services	X		
92025	Weakley	Careall Homecare Services (University HH, LLC)	X		
79556	Shelby	Coram/CVS Specialty Infusion Service		(IN 21 WEST TN COUNTIES)	
36025	Hardin	Deaconess Homecare	X		
19494	Davidson	Elk Valley Health Services Inc	X		
57095	Madison	Extendicare Home Health of West Tennessee	X		
66035	Obion	Extendicare Home Health of Western Tennessee	X		
79206	Shelby	Family Home Health Agency	X		
79496	Shelby	Functional Independence Home Care, Inc	X		
36035	Hardin	Hardin Medical Center Home Health (HMC HH)	NR		
unassigned on 6/10	Shelby	Hemophilia Preferred Care of Memphis	x		
40075	Henry	Henry County Medical Center Home Health	X		
19544	Davidson	Home Care Solutions, Inc	X		
79486	Shelby	Home Health Care of West Tennessee, Inc	X		
79376	Shelby	Homechoice Health Services			(IN 6 WEST TN COUNTIES)
79226	Shelby	Intrepid USA Healthcare Services	X		
57165	Madison	Intrepid USA Healthcare Services (F.C. of TN)	X		
79536	Shelby	Maxim Healthcare Services, Inc.			(IN 6 WEST TN COUNTIES)
57055	Madison	Medical Center Home Health	X		
79106	Shelby	Meritan, Inc.	X		
79316	Shelby	Methodist Alliance Home Care	X		
24026	Fayette	NHC Homecare	X		
27025	Gibson	NHC Homecare	X		
79506	Shelby	No Place Like Home, Inc	X		
79136	Shelby	Quality Home Health Service	X		
23035	Dyer	Regional Home Care - Dyersburg	NR		
57085	Madison	Regional Home Care - Jackson	NR		
39035	Henderson	Regional Home Care - Lexington	NR		
79526	Shelby	Still Waters Home Health Agency	X		
03025	Benton	Tennessee Quality Homecare - Northwest	X		
20045	Decatur	Tennessee Quality Homecare - Southwest	NR		
27085	Gibson	Volunteer Home Care, Inc	X		
20055	Decatur	Volunteer Homecare of West Tennessee	X		
24036	Fayette	Where The Heart Is	X		
79236	Shelby	Willowbrook Visiting Nurse Association	X		

Notes:

1. Excludes 5 agencies that do not serve the Memphis MSA, or more than 2 rural counties in the project service area. Excludes Alere (serves only pregnant women).

2. Asterisks denote 2 of Amedysis' 5 area agencieswho were not surveyed but are assumed to not offer IVIG based on responses of 3 sister Amedysis agencies.

** 3. NR indicates that agency did not respond to multiple phone requests for information.*

The subcontracting option mentioned above should be clarified. Today, if AxelaCare receives a referral from a physician, AxelaCare can deliver AxelaCare pharmaceuticals to the home, but it cannot provide the in-home nursing care -- unless it works through a licensed home health agency in a contracted relationship. However, AxelaCare's experience with subcontractors has not been optimal. In some cases, despite diligent effort, AxelaCare was unable to locate a partnering home health agency that was staffed and willing to provide infusion care promptly upon the physician's request. Response time is an essential consideration. Delay means that the immune-compromised patient must start making multiple burdensome trips to an outpatient or physician infusion center, until home care teams can be activated to serve that patient at home.

Such delays impose risks and avoidable travel and service costs on these immune-compromised patients, who should have been able to start infusions more quickly and economically in their homes without the infection risks of being exposed to other people when traveling to a remote location. And, when the dosages require multiple infusions several days a week, then these sick patients suffer real inconvenience and excessive travel times -- especially if they live many miles from infusion facilities.

Another difficulty being encountered by AxelaCare is that some of its contracted agency nurses have not performed up to company expectations in the use of the CareExchange technology, which requires training and dedication to master and is essential to optimizing quality of care and the compilation of clinically sophisticated databases for AxelaCare's research studies. This advance in "hand-held" or "bedside" technology is valuable to physicians, patients and researchers. It allows AxelaCare to ensure that all meaningful patient data is consistently gathered, is available for use during and after the infusion and is preserved for researching effective treatment strategies for other patients.

Because of these difficulties, the applicant feels that West Tennessee's referring physicians and their immune-compromised patients do not yet have sufficient choice of home health care providers for IVIG therapy. For ***routine*** health care, patients in every West Tennessee county have a choice of 10 to 20 competing providers. But for home infusion of immune globulin medications -- a risky and complex type of ***highly***

specialized care--AxelaCare cannot identify more than one agency that can offer it (including first dosing) timely in more than 6 of the 21 West Tennessee counties. This shortage of choice is in stark contrast to routine home health care. It can be remedied by approving this application.

Letters in the Attachments to this application attest to the need for the AxelaCare nursing program to be allowed into this service area. Three letters, from Shankar Natarajan, M.D., Rahul Sonone,M.D., and Rivers Collison, R.N., are from Memphis Neurology, a five-office physician practice group dealing with disorders of the nervous system. A fourth letter is from Dr. Tulio Bertorini in the Wesley Neurology Clinic, a nine-physician specialty clinic in Memphis focusing on the diagnosis, treatment and research of neurological disorders. There are two letters from Washington, D.C. medical specialty practices who treat Tennessee patients (Tracy Freeman, M.D. and Susan Greenburg, FNP, of National Integrated Health Associates; and Charles Gant, M.D. of International Precision Medicine Associates). A Tennessee patient and Doctor of Pharmacy, Chad Hartman (who lives outside the West Tennessee service area), has written a statement describing the advantage to patients like himself in having a single source to provide both the Immune Globulin pharmaceutical and the nursing care needed to infuse it properly.

B.II.D. DESCRIBE THE NEED TO CHANGE LOCATION OR REPLACE AN EXISTING FACILITY.

Not applicable to a proposed home health agency.

B.II.E. DESCRIBE THE ACQUISITION OF ANY ITEM OF MAJOR MEDICAL EQUIPMENT (AS DEFINED BY THE AGENCY RULES AND THE STATUTE) WHICH EXCEEDS A COST OF $2.0 MILLION; AND/OR IS A MAGNETIC RESONANCE IMAGING SCANNER (MRI), POSITRON EMISSION TOMOGRAPHY (PET) SCANNER, EXTRACORPOREAL LITHOTRIPTER AND/OR LINEAR ACCELERATOR BY RESPONDING TO THE FOLLOWING:

1. For fixed site major medical equipment (not replacing existing equipment):

- **a. Describe the new equipment, including:**
  1. **Total Cost (As defined by Agency Rule);**
  2. **Expected Useful Life;**
  3. **List of clinical applications to be provided; and**
  4. **Documentation of FDA approval.**
- **b. Provide current and proposed schedule of operations.**

2. For mobile major medical equipment:

- **a. List all sites that will be served;**
- **b. Provide current and/or proposed schedule of operations;**
- **c. Provide the lease or contract cost;**
- **d. Provide the fair market value of the equipment; and**
- **e. List the owner for the equipment.**

3. Indicate applicant's legal interest in equipment (e.g., purchase, lease, etc.) In the case of equipment purchase, include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Not applicable. The project does not include major medical equipment.

B.III.A. ATTACH A COPY OF THE PLOT PLAN OF THE SITE ON AN 8-1/2" X 11" SHEET OF WHITE PAPER WHICH MUST INCLUDE:

1. **SIZE OF SITE (IN ACRES);**
2. **LOCATION OF STRUCTURE ON THE SITE;**
3. **LOCATION OF THE PROPOSED CONSTRUCTION; AND**
4. **NAMES OF STREETS, ROADS OR HIGHWAYS THAT CROSS OR BORDER THE SITE.**

PLEASE NOTE THAT THE DRAWINGS DO NOT NEED TO BE DRAWN TO SCALE. PLOT PLANS ARE REQUIRED FOR ALL PROJECTS.

See Attachment B.III.A.

B.III.B.1. DESCRIBE THE RELATIONSHIP OF THE SITE TO PUBLIC TRANSPORTATION ROUTES, IF ANY, AND TO ANY HIGHWAY OR MAJOR ROAD DEVELOPMENTS IN THE AREA. DESCRIBE THE ACCESSIBILITY OF THE PROPOSED SITE TO PATIENTS/CLIENTS.

In a home health project, the site of service is the patient home, which can be in any service area county. The table on the following page shows the drive time and distances between the proposed home office in Shelby County and a major community in each of the 21 counties in the proposed service area of the project.

But the distance between the counties and the Memphis home office is not particularly meaningful because AxelaCare field nurses will be located in communities across the service area -- not just in Memphis.

Field nurses' points of origin for making home visits cannot be known until they are employed. So, the applicant cannot predict the geographical distribution of its field-based nursing staff outside Shelby County. However, AxelaCare obviously will distribute its nurses in such a way as to make their drive times to patients acceptable, and to make service to outlying rural counties a reality. One probable option will be stationing one or more nurses in Madison County and/or adjacent counties.

Table Two: Mileage and Drive Times Between Home Office and Major Communities in the Primary Service Area			
County	**Community**	**Distance**	**Drive Time**
1. Benton	Camden	136 mi.	132 min.
2. Carroll	Huntingdon	110 mi.	113 min.
3. Chester	Henderson	79.4 mi.	100 min.
4.Crockett	Alamo	72.1 mi.	85 min.
5. Decatur	Decaturville	123 mi.	131 min.
6. Dyer	Dyersburg	76.9 mi.	98 min.
7. Fayette	Somerville	49.0 mi.	53 min.
8. Gibson	Milan	95.0 mi.	110 min.
9. Hardeman	Bolivar	67.7 mi.	74 min.
10. Hardin	Savannah	115.0 mi.	121 min.
11. Haywood	Brownsville	54.7 mi.	61 min.
12. Henderson	Lexington	102.0 mi.	103 min.
13. Henry	Paris	136 mi.	141 min.
14. Lake	Tiptonville	111 mi.	138 min.
15. Lauderdale	Ripley	63.0 mi.	84 min.
16. Madison	Jackson	79.3 mi.	82 min.
17. McNairy	Selmer	91.1 mi.	99 min.
18. Obion	Union City	116.0 mi.	141 min.
19. Shelby	Memphis	NA	NA
20. Tipton	Covington	40.4 mi.	59 min.
21. Weakley	Martin	126.0 mi.	137 min.

Source: Google Maps, 4-21-16.

Note: Home office is at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, 38137.

B.IV. ATTACH A FLOOR PLAN DRAWING FOR THE FACILITY WHICH INCLUDES PATIENT CARE ROOMS (NOTING PRIVATE OR SEMI-PRIVATE), ANCILLARY AREAS, EQUIPMENT AREAS, ETC.

See attachment B.IV.

IV. FOR A HOME CARE ORGANIZATION, IDENTIFY

1. **EXISTING SERVICE AREA (BY COUNTY);**
2. **PROPOSED SERVICE AREA (BY COUNTY);**
3. **A PARENT OR PRIMARY SERVICE PROVIDER;**
4. **EXISTING BRANCHES AND/OR SUB-UNITS; AND**
5. **PROPOSED BRANCHES AND/OR SUBUNITS.**

Not applicable. The application is not for a home care organization.

C(I) NEED

C(I).1. DESCRIBE THE RELATIONSHIP OF THIS PROPOSAL TO THE IMPLEMENTATION OF THE STATE HEALTH PLAN AND TENNESSEE'S HEALTH: GUIDELINES FOR GROWTH.

A. PLEASE PROVIDE A RESPONSE TO EACH CRITERION AND STANDARD IN CON CATEGORIES TIIAT ARE APPLICABLE TO THE PROPOSED PROJECT. DO NOT PROVIDE RESPONSES TO GENERAL CRITERIA AND STANDARDS (PAGES 6-9) HERE.

B. APPLICATIONS THAT INCLUDE A CHANGE OF SITE...(Not appllicable to this project)

Guidelines for Growth 2000: Project-Specific Guidelines
Home Health Services

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
3. Using recognized population sources, projections for four years into the future will be used.
4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

This "need" projection is made by the Tennessee Department of Health (TDH). The most current version is a 2015-2020 projection of need by county. The TDH projections for this project's service area are attached on the following page. None of its 21 counties is projected to have an unmet generic need for additional home healthcare services.

However, that projection is neither accurate nor relevant to this specialty project. First, the projection methodology is stated as a "general guideline" and it uses a simple 1.5% planning factor for each county's population. A one-size-fits all methodology is not informative for such a specialized "niche" need as immune-compromised patients seeking IVIG therapy. Second, the Guidelines projection methodology -- which predated the rising importance of home care -- is seriously outdated on its face. There were 39,117 actual home health agency patients served in 2015 (an evidence-based indicator of need). That utilization was 61.7% higher than the 24,186 patients that the 1.5% formula would have predicted as "needed" in this service area. This fact, standing alone, confirms that the formula does not accurately predict need or utilization.

Joint Annual Report of Home Health Agencies - 2015 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2020 vs. 2015)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2015 Pop.	Use Rate	Projected 2020 Pop.	Projected Capacity	Projected Need (.015 x 2020 Pop.)	Need or (Surplus) for 2020
Tennessee	1,635	1,473	170,384	6,735,706	0.0252956409	7,108,031	179,802	106,620	(73,182)
Benton	12	11	684	16,655	0.0410687481	16,741	688	251	(436)
Carroll	13	13	1,465	28,430	0.0515300739	28,207	1,454	423	(1,030)
Chester	13	13	545	18,076	0.0301504758	18,978	572	285	(288)
Crockett	12	11	567	14,845	0.0381946783	15,080	576	226	(350)
Decatur	15	15	648	11,939	0.0542759025	12,077	655	181	(474)
Dyer	9	9	1,902	39,155	0.0485761716	39,872	1,937	598	(1,339)
Fayette	21	20	707	43,631	0.0162040751	48,510	786	728	(58)
Gibson	14	14	1,870	51,119	0.0365813103	52,438	1,918	787	(1,132)
Hardeman	15	14	920	27,285	0.0337181602	27,278	920	409	(511)
Hardin	16	15	1,101	26,479	0.0415801201	26,783	1,114	402	(712)
Haywood	15	13	649	18,477	0.0351247497	18,128	637	272	(365)
Henderson	12	12	1,209	29,101	0.0415449641	30,298	1,259	454	(804)
Henry	11	10	1,270	33,267	0.0381759702	34,055	1,300	511	(789)
Lake	7	6	357	8,230	0.0433778858	8,579	372	129	(243)
Lauderdale	14	12	907	28,529	0.0317922114	29,186	928	438	(490)
McNairy	14	14	1,138	27,019	0.0421185092	27,760	1,169	416	(753)
Madison	18	17	3,220	102,429	0.0314364096	106,352	3,343	1,595	(1,748)
Obion	10	10	1,314	31,722	0.0414223567	31,559	1,307	473	(834)
Shelby	26	26	16,269	953,899	0.0170552648	981,022	16,732	14,715	(2,016)
Tipton	21	19	1,172	66,234	0.0176948395	71,196	1,260	1,068	(192)
Weakley	15	15	1,203	35,894	0.0335153508	36,360	1,219	545	(673)
PSA TOTAL	303	289	39,117	1,612,415		1,660,459	40,146	24,906	(15,237)

*Most recent year of Joint Annual Report data for Home Health Agencies
Data is projected four years from the year the Home Health data was **finalized, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.
Note: Population data will not match the UTCBER data exactly due to rounding.

The State Health Plan and the *Guidelines for Growth* appropriately focus on home health needs in general for an entire population; but this specialty project should not be disqualified from consideration on the basis of this plainly outdated and unreliable formula. This is especially true because other criteria in the *Guidelines* recognize the need to consider local physician and patient viewpoints about current needs; and those viewpoints strongly support this application.

5. Documentation from referral sources:

a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

The applicant is providing letters of referral support from referring physicians and others. Please see the Attachments.

b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant will serve referrals of only one type of patient: those who need immune globulin infusions, or the IVIG patient. These are immune-compromised patients.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant is providing letters of support from these patients. Please see the Attachments.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

As discussed at length in Section B.II.C. above (Need for the Project), AxelaCare proposes to provide a type of infusion service that is very different from services provided by almost all other agencies in the area. AxelaCare's program will:

• provide home infusion only for the immune-compromised patient, whose physician specialist prescribes infusions of AxelaCare's own immune globulin products and refers patients to AxelaCare to arrange immediate infusion services;

• utilizc only highly skilled registered nurses who have documented competency in managing IVIG infusions and seek all available certifications for this specialty care process;

• mobilize and deploy the infusion team of nurse and pharmacist as rapidly as required to allow the patient to receive the first infusion at home -- thereby avoiding the increased costs, inconveniences and risks of commuting to distant infusion centers or outpatient acute care facilities;

• provide care for the 2-10 hour sessions that immune globulin recipients require on multiple visits for prolonged periods of time;

• provide state-of-the-art "bed-side" technology for complete, accurate and real-time documentation of the infusion process and patient reactions, and for communicating that to the treatment team pharmacist and the referring physician during and after the infusion when the need arises,.

• gather and preserve real-time patient clinical data that is useful to academic research in this rapidly evolving area of medicine.

The applicant is aware of only one licensed home health agency that can provide all of these advantages to immune-compromised patients in all 21 West Tennessee counties--rural ones as well as urbanized ones. Two other agencies have similar clinical capability but they are not authorized to provide it outside of six urban counties in the service area. This extreme lack of choice for patients is in stark contrast to the abundant choice that physicians and patients enjoy for ***routine*** home health care (10-20 agencies for every county). Consumers who are immune-compromised are disadvantaged by this lack of choice. They and their physicians deserve reasonable options for high-quality and responsive specialty IVIG therapy, just as they enjoy for routine home care.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

a. The average cost per visit by service category shall be listed.

b. The average cost per patient based upon the projected number of visits per patients shall be listed.

As explained in Section C.II.6.A below, AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a "gross charge" that is discounted by "contractual adjustments" to yield "net revenue". The revenue figures shown in Section B of the Projected Data Charts are the billed or "expected" revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts before deductions for charity and bad debt.

The table below shows the average expected charge/revenue data per patient and per visit for AxelaCare's nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three: Axela Health Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)

	Year One--CY2017	Year Two-CY2018
Expected Nursing Revenue	$259,200	$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	$240	$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	$5,760	$5,760

Table Four on the second following page provides available charge and cost information filed by area home health agencies in their most recent 2015 Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. The data do not allow a meaningful comparison to AxelaCare's very different pricing structure.

AxelaCare pays its infusion nurses between $37 and $45 per hour; an average is approximately $40 per hour. AxelaCare projects Year One (2017) average expected nursing revenues of $240 per visit.

The only comparable specialty infusion-specific charge data identified by the applicant in publicly available sources was CN1406-018, approved in 2014 for Coram/CVS Specialty Infusion Services to do specialty home infusion care. In that document, Coram projected average charges for its "specialty infusion patient" at $290-$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections. The Coram 2015 Joint Annual Report provides no data on average charges. It is Coram's first such report since becoming operational in late 2015.

For existing home health agencies as a group, the table on the next page shows that those who reported JAR financial data had an average cost per visit of $105.86, an average charge per visit of $103.33, and an average charge per hour of $29.58.

Table Four: Comparative 2015 Cost and Charge Data Reported by West Tennessee Agencies Skilled Nursing Only

Health Statistics ID	Agency County	License Number	Agencies (52)	Cost per Visit	Avg Chg per Visit	Avg Chg per Hour
03025	Benton	8	Tennessee Quality Homecare - Northwest	52.00		
09065	Carroll	19	Baptist Memorial Home Care & Hospice	204.00		
19494	Davidson	42	Elk Valley Health Services Inc		$79.00	$35.00
19544	Davidson	56	Home Care Solutions, Inc	90.00		
20045	Decatur	221	Tennessee Quality Homecare - Southwest	50.00		
20055	Decatur	63	Volunteer Homecare of West Tennessee	88.00	$120.00	$40.00
23035	Dyer	77	Regional Home Care - Dyersburg	61.00		
24026	Fayette	291	NHC Homecare	111.00		
24036	Fayette	612	Where The Heart Is	60.00		
27025	Gibson	85	NHC Homecare	91.00		
27085	Gibson	285	Volunteer Home Care, Inc	105.00	$120.00	$40.00
33103	Hamilton	113	Amedisys Home Health	41.00		
36025	Hardin	290	Deaconess Homecare	144.00		
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)	99.00		
38015	Haywood	288	Careall Homecare Services	82.00		$25.00
39035	Henderson	139	Regional Home Care - Lexington	57.00		
40075	Henry	122	Henry County Medical Center Home Health	188.00		
41034	Hickman	125	St. Thomas Home Health	98.00		
57055	Madison	174	Medical Center Home Health	97.00		
57075	Madison	177	Amedisys Home Health Care	46.00		
57085	Madison	178	Regional Home Care - Jackson	80.00		
57095	Madison	120	Extendicare Home Health of West Tennessee	100.00		
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)	136.00		
60024	Maury	181	NHC Homecare	110.00		
60074	Maury	194	Careall Homecare Services	101.00		$23.00
66035	Obion	188	Extendicare Home Health of Western Tennessee	102.00		
79106	Shelby	237	Meritan, Inc.	143.00		
79136	Shelby	224	Quality Home Health Service (Extended Health Care, Inc.)	110.00		
79146	Shelby	239	Amedisys Home Care	62.00		
79206	Shelby	229	Family Home Health Agency	196.00		
79226	Shelby	214	Intrepid USA Healthcare Services	136.00		
79236	Shelby	244	Willowbrook Visiting Nurse Association	99.00		
79246	Shelby	215	Amedisys Home Health Care	54.00		
79256	Shelby	216	Americare Home Health Agency, Inc	150.00		
79276	Shelby	241	Baptist Trinity Home Care	177.00		
79316	Shelby	233	Methodist Alliance Home Care	160.00		
79376	Shelby	240	Homechoice Health Services	108.00	$66.00	$15.00
79386	Shelby	238	Amedisys Tennessee, LLC (Amedisys HH)	54.00		
79446	Shelby	242	Baptist Trinity Home Care - Private Pay (1 Patient only)		$155.00	$45.00
79456	Shelby	347	Accredo Health Group, Inc			
79466	Shelby	459	Alere Women's and Children's Health LLC			
79486	Shelby	227	Home Health Care of West Tennessee, Inc	123.00		$33.00
79496	Shelby	610	Functional Independence Home Care, Inc			
79506	Shelby	611	No Place Like Home, Inc			$35.00
79526	Shelby	616	Still Waters Home Health Agency	65.00		
79536	Shelby	618	Maxim Healthcare Services, Inc.		$80.00	$38.00
79546	Shelby	621	Best Nurses, Inc.			
79556	Shelby	120	Coram CVS/Specialty Infusion Service			
92025	Weakley	276	Careall Homecare Services	83.00		$26.00
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice	178.00		
96020	Fulton Co., KY	297	Regional Home Care Parkway	155.00		
	Shelby		Hemophilia Preferred Care of Memphis			
Average of Agencies Reporting Costs & Charges				105.86	103.33	29.58

Note: Hemophilia Preferred Care of West Tennessee Not Yet Licensed and Operating as of ------.

Source: Joint Annual Reports of Home Health Agencies

The Framework for Tennessee's Comprehensive State Health Plan
Five Principles for Achieving Better Health

The following Five Principles for Achieving Better Health serve as the basic framework for the State Health Plan. After each principle, the applicant states how this CON application supports the principle, if applicable.

1. Healthy Lives

The purpose of the State Health Plan is to improve the health of Tennesseans.
Every person's health is the result of the interaction of individual behaviors, society, the environment, economic factors, and our genetic endowment. The State Health Plan serves to facilitate the collaboration of organizations and their ideas to help address health at these many levels.

Authorization of AxelaCare to provide home infusion nursing will address the needs of immune-compromised IVIG recipients to obtain AxelaCare medications in the most economical setting, without incurring needless extra time in the hospital for first dosages. Approval will eliminate burdensome commuting to remote infusion facilities, or having added risks of infections through exposure to other persons when they go to those infusion facilities.

2. Access to Care

Every citizen should have reasonable access to health care.
Many elements impact one's access to health care, including existing health status, employment, income, geography, and culture. The State Health Plan can provide standards for reasonable access, offer policy direction to improve access, and serve a coordinating role to expand health care access.

Provision of the proposed service to all of the region's 21 counties will improve access to this type of care for rural residents of the region, whose counties are not served by a choice of home IVIG infusion providers. Those using AxelaCare home nursing teams will be spared multiple long drives to remote infusion centers.

3. Economic Efficiencies

The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies and the continued development of the state's health care system. **The State Health Plan should work to identify opportunities to improve the efficiency of the state's health care system and to encourage innovation and competition.**

This type of patient, in this region of Tennessee, deserves expansion of choice among specialty providers of IVIG home infusion care. Only one known provider of this

service now serves all West Tennessee counties, and two other agencies provide it only in urban area counties. This compares poorly to the 10-20 agencies serving those counties for more routine home health needs. This project encourages reasonable levels of provider competition, and allows into the market an innovative national home care provider whose infusion management technology is valuable to the entire caregiver team.

4. Quality of Care

Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers. **Health care providers are held to certain professional standards by the state's licensure system. Many health care stakeholders are working to improve their quality of care through adoption of best practices and data-driven evaluation.**

The applicant has a robust quality assurance program, in which regional and corporate clinical staff continuously review patient data to ensure that AxelaCare nurses maintain the highest standard of competence and provide the best possible patient outcomes for every infusion session. The CareExchange technology used by AxelaCare nurses facilitates achieving optimal care during the infusion itself, allowing pharmacist and physician team members to participate in treatment decisions real-time as infusion proceeds, reflecting changing patient needs for changes in dosage amounts, infusion rates, and other services. The AxelaCare program ensures the highest possible quality of treatment outcomes in this difficult and complex area of care.

5. Health Care Workforce

The state should support the development, recruitment, and retention of a sufficient and quality health care workforce. **The state should consider developing a comprehensive approach to ensure the existence of a sufficient, qualified health care workforce, taking into account issues regarding the number of providers at all levels and in all specialty and focus areas, the number of professionals in teaching positions, the capacity of medical, nursing, allied health and other educational institutions, state and federal laws and regulations impacting capacity programs, and funding.**

The project provides additional assurances to physicians and patients that their home infusion provider will be of the highest level of competence. Staffing the project will create an experienced and highly qualified specialty nursing staff for expanded service to rural counties as well as the urbanized Memphis area.

C(I).2. DESCRIBE THE RELATIONSHIP OF THIS PROJECT TO THE APPLICANT'S LONG-RANGE DEVELOPMENT PLANS, IF ANY.

AxelaCare's goal is to become a Statewide provider of specialty home infusion nursing care for a very small group of West Tennessee patients whose physicians have prescribed infusion of AxelaCare immune globulin pharmaceuticals. Similar limited-scope applications for Middle and East Tennessee may be filed in the future, to achieve Statewide immune globulin home care for this patient group.

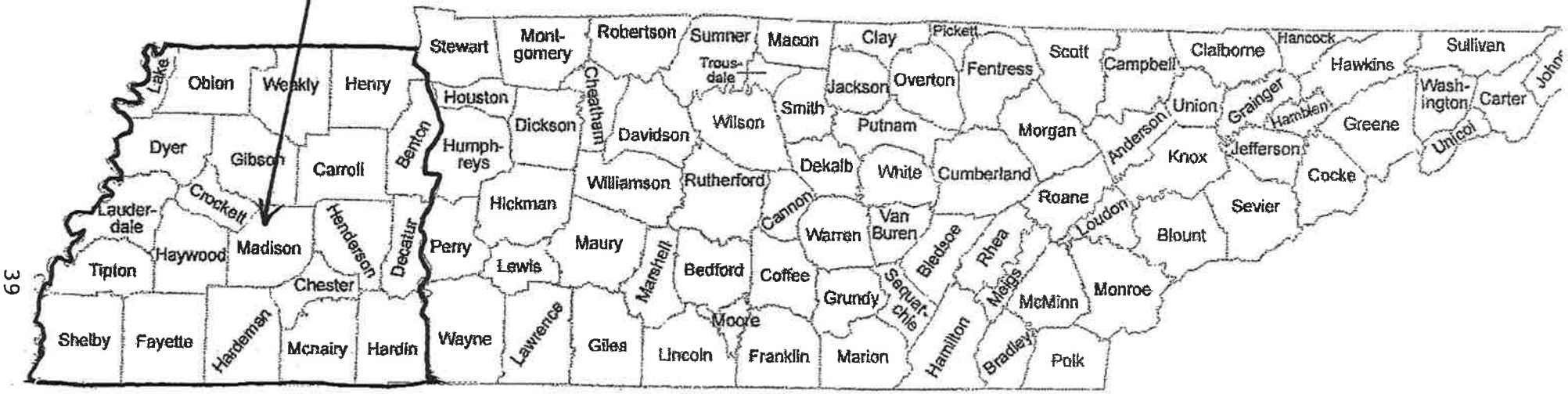
C(I).3. IDENTIFY THE PROPOSED SERVICE AREA AND JUSTIFY THE REASONABLENESS OF THAT PROPOSED AREA. SUBMIT A COUNTY-LEVEL MAP INCLUDING THE STATE OF TENNESSEE CLEARLY MARKED TO REFLECT THE SERVICE AREA. PLEASE SUBMIT THE MAP ON A 8-1/2" X 11" SHEET OF WHITE PAPER MARKED ONLY WITH INK DETECTABLE BY A STANDARD PHOTOCOPIER (I.E., NO HIGHLIGHTERS, PENCILS, ETC.).

The proposed service area consists of 21 Tennessee counties. These are Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties. A map showing the area's location within Tennessee is provided following this page, and also in the Attachments to the application.

The applicant also has provided in the Attachments (Miscellaneous section) a projected patient origin for the project's patients, and the most current State report showing which agencies are now utilized by residents of these counties for all home care needs. Again, the applicant notes that the service proposed by this application is not currently available areawide, on a timely basis, from more than one of the many agencies authorized to provide home care in West Tennessee.

This is a reasonable area to cover. Nurses who will provide the proposed home care will reside throughout the region, so that they have acceptable drive times to the patients' homes. For example, there will be nurses residing in both Memphis and Jackson. Table Six-A in this application shows that five of the area's home health agencies are licensed to serve all twenty-one counties, and eight of them serve nineteen or more of the twenty-one counties. For home health services, whose nurses are typically residing in multiple locations in the service area, a large regional service area such as West Tennessee is not unusual or impractical.

AXELACARE WEST TENNESSEE
PROJECT SERVICE AREA



C(I).4.A DESCRIBE THE DEMOGRAPHICS OF THE POPULATION TO BE SERVED BY THIS PROPOSAL.

The service area's median age is 39.9 years, which is close to the Tennessee average of 38.0 (2010 census). The service area's total population is increasing more slowly than the State's total population.

Whereas infusion services are needed in particular by the elderly population, this project will serve primarily patients below the age of 65, who are inordinately subject to neurological conditions regarded as immune system disorders.

The service area's population under the age of 65 is 85.4% of the total population, increasing to 85.6% over the next five years. These percentages are similar to the corresponding State percentages. The area population younger than 65 is increasing slowly -- at 0.2% annually, compared to the Statewide rate of 2.1%.

West Tennessee's rates of TennCare enrollment and of persons living in poverty are higher than Tennessee's rates. An estimated 27.4% of the service area residents are enrolled in TennCare, compared to 22.0% statewide. An estimated 22.0% of service area residents live in poverty, compared to 18.3% statewide.

Table Five on the following page provides detailed demographic statistics for each service area county.

Table Five: AlexaCare Health Solutions--West Tennessee
Demographic Characteristics of Primary Service Area Population To Be Served By the Project
2016-2020

Primary Service Area Counties	Median Age - 2010 Census	Total Population 2016	Total Population 2020	Total Population % Change 2016 - 2020	Total Population <Age 65 2016	% of Population	Total Population < Age 65 2020	% of Population	< 65 Age Population - Change 2016 - 2020	Median Household Income	TennCare Enrollees Mar 2016	Percent of 2015 Population Enrolled in TennCare	Persons Below Poverty Level 2015	Persons Below Poverty Level as % of Population US Census
Benton	45.4	16,672	16,741	0.4%	12,557	75.3%	12,173	73.0%	-3.1%	$34,087	4,351	26.1%	3,568	21.4%
Carroll	42.0	28,380	28,207	-0.6%	22,388	78.9%	21,706	76.5%	-3.0%	$36,168	8,059	28.4%	5,903	20.8%
Chester	36.2	18,260	18,978	3.9%	15,089	82.6%	15,388	84.3%	2.0%	$41,028	4,034	22.1%	3,670	20.1%
Crockett	39.6	14,884	15,080	1.3%	12,076	81.1%	12,001	80.6%	-0.6%	$37,298	4,150	27.9%	2,828	19.0%
Decatur	44.3	11,963	12,077	1.0%	9,033	75.5%	8,814	73.7%	-2.4%	$37,219	3,044	25.4%	2,381	19.9%
Dyer	39.3	39,306	39,872	1.4%	32,453	82.6%	32,235	82.0%	-0.7%	$41,426	11,269	28.7%	7,704	19.6%
Fayette	41.9	44,637	48,510	8.7%	35,906	80.4%	37,339	83.7%	4.0%	$55,623	7,191	16.1%	6,562	14.7%
Gibson	39.9	51,394	52,438	2.0%	42,003	81.7%	42,183	82.1%	0.4%	$37,460	13,736	26.7%	10,022	19.5%
Hardeman	39.2	27,283	27,278	0.0%	22,647	83.0%	22,107	81.0%	-2.4%	$30,260	7,467	27.4%	6,903	25.3%
Hardin	43.5	26,557	26,783	0.9%	20,567	77.4%	20,102	75.7%	-2.3%	$34,084	7,573	28.5%	5,763	21.7%
Haywood	39.2	18,410	18,128	-1.5%	15,333	83.3%	14,484	78.7%	-5.5%	$33,922	6,119	33.2%	4,547	24.7%
Henderson	39.7	29,349	30,298	3.2%	24,112	82.2%	24,339	82.9%	0.9%	$38,696	7,527	25.6%	5,606	19.1%
Henry	44.3	33,439	34,055	1.8%	25,511	76.3%	25,096	75.1%	-1.6%	$38,694	8,450	25.3%	6,855	20.5%
Lake	38.3	8,299	8,579	3.4%	7,019	84.6%	7,180	86.5%	2.3%	$29,214	2,311	27.8%	3,477	41.9%
Lauderdale	36.4	28,658	29,186	1.8%	24,574	85.7%	24,608	85.9%	0.1%	$31,185	8,300	29.0%	7,107	24.8%
Madison	36.8	103,234	106,352	3.0%	86,953	84.2%	87,409	84.7%	0.5%	$42,069	25,846	25.0%	21,576	20.9%
McNairy	41.6	27,179	27,760	2.1%	21,549	79.3%	21,432	78.9%	-0.5%	$32,214	8,044	29.6%	6,387	23.5%
Obion	41.4	31,692	31,559	-0.4%	25,356	80.0%	24,662	77.8%	-2.7%	$40,327	8,365	26.4%	6,592	20.8%
Shelby	34.6	959,361	981,022	2.3%	842,527	87.8%	845,788	88.2%	0.4%	$46,213	276,265	28.8%	220,653	23.0%
Tipton	36.6	67,250	71,196	5.9%	58,118	86.4%	60,152	89.4%	3.5%	$53,133	14,205	21.1%	10,357	15.4%
Weakley	37.0	36,066	36,360	0.8%	29,662	82.2%	29,241	81.1%	-1.4%	$35,845	7,766	21.5%	7,754	21.5%
Tennessee PSA	39.9	1,622,273	1,660,459	2.4%	1,385,433	85.4%	1,388,439	85.6%	0.2%	$38,389	444,072	27.4%	356,214	22.0%
State of Tennessee	38.0	6,812,005	7,108,031	4.3%	5,720,489	84.0%	5,841,736	85.8%	2.1%	$44,621	1,525,548	22.4%	1,246,597	18.3%

Sources: TDOH Population Projections, 2015; U.S. Census QuickFacts; TennCare Bureau.
PSA data is unweighted average, or total, of county data.

C(I).4.B. DESCRIBE THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION, INCLUDING HEALTH DISPARITIES, THE ACCESSIBILITY TO CONSUMERS, PARTICULARLY THE ELDERLY, WOMEN, RACIAL AND ETHNIC MINORITIES, AND LOW-INCOME GROUPS. DOCUMENT HOW THE BUSINESS PLANS OF THE FACILITY WILL TAKE INTO CONSIDERATION THE SPECIAL NEEDS OF THE SERVICE AREA POPULATION.

These factors have been discussed extensively in B.II.C. and other sections of the application. The applicant's experience is that commercially insured patients seeking home infusion of immune globulin pharmaceuticals often experience difficulties in obtaining home nursing to administer first and subsequent medication doses in a timely way.

As a consequence, those immune-compromised patients are forced to remain in the hospital for more (expensive) days than necessary to begin infusions pending creation of a competent home nursing team. Or, they must begin traveling back and forth to a freestanding or practice-based infusion center. This second option involves burdensome drive times and additional risks of exposure to opportunistic infections.

The project meets the special needs of a very small, but very compromised, patient population that is well-known to the applicant through its long experience in many other States.

West Tennessee's rural counties have an immediate need for an additional provider of immune globulin home infusion services.

Although Medicare rules deny reimbursement for home services of this type for Medicare enrollees, the applicant will serve all other types of adequately insured patients, regardless of their age, gender, race, ethnicity or income. And, based on its national experience, the applicant projects providing charity care of 2% of expected revenue receipts (before bad debt deductions).

C(I).5. DESCRIBE THE EXISTING OR CERTIFIED SERVICES, INCLUDING APPROVED BUT UNIMPLEMENTED CON'S, OF SIMILAR INSTITUTIONS IN THE SERVICE AREA. INCLUDE UTILIZATION AND/OR OCCUPANCY TRENDS FOR EACH OF THE MOST RECENT THREE YEARS OF DATA AVAILABLE FOR THIS TYPE OF PROJECT. BE CERTAIN TO LIST EACH INSTITUTION AND ITS UTILIZATION AND/OR OCCUPANCY INDIVIDUALLY. INPATIENT BED PROJECTS MUST INCLUDE THE FOLLOWING DATA: ADMISSIONS OR DISCHARGES, PATIENT DAYS, AND OCCUPANCY....

Tables on the following pages identify all home health agencies currently authorized to serve this area, and provide utilization statistics for them.

Tables

- Tables Six-A, B: Service area counties that are authorized for each approved agency.
- Tables Seven-A, B: Patients served during 2015, in each agency's authorized counties within the project service area.
- Tables Eight-A, B, C: Area agencies' patient utilization 2013-2015, with agencies' dependence on patients from the project service area.
- Tables Nine-A, B, C: Agencies' TennCare gross revenues (charges) as a percent of their total gross revenues, and a ranking by level of TennCare participation.

Remarks

1. There are fifty-two agencies approved to serve this project's 21-county service area. Two are not currently licensed.
2. Only 1 in 10 of the agencies (i.e., 5 agencies) are authorized to serve all 21 of the project service area counties.
3. The agencies served 39,026 home care patients in the service area in 2015.
4. Their 2015 patient utilization was 6.1% higher than two years before, in 2013.
5. If this rate of increase continues, then in 2017--this project's Year Two of operation--the existing agencies will serve 3,092 more patients (50,652 X 1.061%).
6. The applicant's projected 65 patients in Year Two equate to less than two-tenths of one percent (0.17%) of all the agencies' total caseloads in 2015.
7. The agencies' 34.4% *average* TennCare utilization is misleading. Only 11 agencies had a TennCare mix of 34% or higher. Almost half the agencies (24) had zero participation and 9 more had lower than 10% participation.

Table Six-A: Project Service Area Counties Authorized for Existing Home Health Agencies--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agencies (52)	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Number of Counties Served
79456	Shelby	347	Accredo Health Group, Inc						x		x		x				x				x	x		6
79466	Shelby	459	Alere Women's and Children's Health LLC	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
79146	Shelby	239	Amedisys Home Care						x													x	x		3
33103	Hamilton	113	Amedisys Home Health									x							x						2
57075	Madison	177	Amedisys Home Health Care	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x		x	x	19
79246	Shelby	215	Amedisys Home Health Care						x													x	x		3
79386	Shelby	238	Amedisys Tennessee, LLC						x								x					x	x		4
79256	Shelby	216	Americare Home Health Agency, Inc																			x	x		2
09065	Carroll	19	Baptist Memorial Home Care & Hospice	x	x	x	x	x			x				x	x			x					x	10
79276	Shelby	241	Baptist Trinity Home Care				x		x	x		x		x				x				x	x		8
79446	Shelby	242	Baptist Trinity Home Care - Private Pay							x		x		x								x	x		5
79546	Shelby	621	Best Nurses, Inc.						x													x	x		3
38015	Haywood	288	Careall Homecare Services	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x		x	x	19
60074	Maury	194	Careall Homecare Services					x				x								x					3
92025	Weakley	276	Careall Homecare Services	x	x		x		x		x					x	x		x		x			x	10
79556	Shelby	120	Coram CVS/Specialty Infusion Service	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
36025	Hardin	290	Deaconess Homecare			x		x			x	x	x	x				x	x						8
19494	Davidson	42	Elk Valley Health Services Inc	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
57095	Madison	120	Extendicare Home Health of West Tennessee	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
66035	Obion	188	Extendicare Home Health of Western Tennessee						x		x						x				x			x	5
79206	Shelby	229	Family Home Health Agency						x													x			2
79496	Shelby	610	Functional Independence Home Care, Inc						x													x	x		3
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)			x		x				x								x					4
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis																			x			1
40075	Henry	122	Henry County Medical Center Home Health	x	x										x									x	4
19544	Davidson	56	Home Care Solutions, Inc	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
79486	Shelby	227	Home Health Care of West Tennessee, Inc						x								x					x	x		4
79376	Shelby	240	Homechoice Health Services						x		x		x				x					x	x		6
79226	Shelby	214	Intrepid USA Healthcare Services						x													x	x		3
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)		x	x	x	x		x	x	x	x	x	x			x	x	x			x	x	15
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice									x								x					2
79536	Shelby	618	Maxim Healthcare Services, Inc.						x		x		x					x				x	x		6
57055	Madison	174	Medical Center Home Health	x	x	x	x	x	x		x	x	x	x	x	x	x		x	x	x			x	17
79106	Shelby	237	Meritan, Inc.																			x			1
79316	Shelby	233	Methodist Alliance Home Care					x	x		x		x					x				x	x		7
24026	Fayette	291	NHC Homecare						x		x		x					x	x	x		x	x		8
27025	Gibson	85	NHC Homecare	x	x	x	x	x	x		x				x	x			x		x			x	12
60024	Maury	181	NHC Homecare									x													1
79506	Shelby	611	No Place Like Home, Inc						x													x	x		3
79136	Shelby	224	Quality Home Health Service						x		x		x					x				x	x		6
23035	Dyer	77	Regional Home Care - Dyersburg				x		x		x						x	x			x				6
57085	Madison	178	Regional Home Care - Jackson	x	x	x	x	x	x	x	x	x	x	x	x			x	x	x	x		x	x	19
39035	Henderson	139	Regional Home Care - Lexington	x	x	x	x	x		x	x	x	x	x	x				x	x				x	15
96020	Fulton Co., KY	297	Regional Home Care Parkway																					x	1
41034	Hickman	125	St. Thomas Home Health	x																					1
79526	Shelby	616	Still Waters Home Health Agency																			x			1
03025	Benton	8	Tennessee Quality Homecare - Northwest	x	x			x			x				x	x			x		x			x	9
20045	Decatur	221	Tennessee Quality Homecare - Southwest	x		x		x				x			x				x	x					7
27085	Gibson	285	Volunteer Home Care, Inc	x	x		x		x		x					x	x		x		x			x	10
20055	Decatur	63	Volunteer Homecare of West Tennessee		x	x		x		x	x	x			x	x			x	x				x	11
24036	Fayette	612	Where The Heart Is						x													x	x		3
79236	Shelby	244	Willowbrook Visiting Nurse Association						x		x		x				x					x	x		6
			Agencies Availablee to Each County	**18**	**18**	**17**	**17**	**19**	**16**	**29**	**19**	**22**	**19**	**21**	**17**	**17**	**10**	**19**	**21**	**19**	**15**	**28**	**28**	**20**	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table Six-B: Project Service Area Counties Authorized to be Served by Existing Home Health Agencies--BY AGENCY ID NUMBER

Health Statistics ID	Agency County	License Number	Agencies (52)	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Number of Counties Served
03025	Benton	8	Tennessee Quality Homecare - Northwest	x	x			x			x				x	x			x		x			x	9
09065	Carroll	19	Baptist Memorial Home Care & Hospice	x	x	x	x	x			x				x	x			x					x	10
19494	Davidson	42	Elk Valley Health Services Inc	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
19544	Davidson	56	Home Care Solutions, Inc	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
20045	Decatur	221	Tennessee Quality Homecare - Southwest	x		x		x					x		x				x	x					7
20055	Decatur	63	Volunteer Homecare of West Tennessee		x	x		x			x	x	x		x	x			x	x				x	11
23035	Dyer	77	Regional Home Care - Dyersburg				x		x		x						x	x			x				6
24026	Fayette	291	NHC Homecare							x		x		x				x	x	x			x	x	8
24036	Fayette	612	Where The Heart Is							x													x	x	3
27025	Gibson	85	NHC Homecare	x	x	x	x	x	x		x				x	x			x		x			x	12
27085	Gibson	285	Volunteer Home Care, Inc	x	x		x		x		x					x	x		x		x			x	10
33103	Hamilton	113	Amedisys Home Health									x								x					2
36025	Hardin	290	Deaconess Homecare			x		x				x	x	x	x				x	x					8
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)			x		x					x							x					4
38015	Haywood	288	Careall Homecare Services	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x			x	19
39035	Henderson	139	Regional Home Care - Lexington	x	x	x	x	x		x	x	x	x	x	x	x			x	x				x	15
40075	Henry	122	Henry County Medical Center Home Health	x	x											x								x	4
41034	Hickman	125	St. Thomas Home Health	x																					1
57055	Madison	174	Medical Center Home Health	x	x	x	x	x	x		x	x	x	x	x	x	x		x	x	x			x	17
57075	Madison	177	Amedisys Home Health Care	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x		x	x	19
57085	Madison	178	Regional Home Care - Jackson	x	x	x	x	x	x	x	x	x	x	x	x	x		x	x	x	x		x	x	19
57095	Madison	120	Extendicare Home Health of West Tennessee	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)		x	x	x	x		x	x	x	x	x	x			x	x	x			x	x	15
60024	Maury	181	NHC Homecare									x													1
60074	Maury	194	Careall Homecare Services					x				x								x					3
66035	Obion	188	Extendicare Home Health of Western Tennessee						x		x						x				x			x	5
79106	Shelby	237	Meritan, Inc.																			x			1
79136	Shelby	224	Quality Home Health Service							x		x						x				x	x		6
79146	Shelby	239	Amedisys Home Care							x												x	x		3
79206	Shelby	229	Family Home Health Agency							x												x			2
79226	Shelby	214	Intrepid USA Healthcare Services							x												x	x		3
79236	Shelby	244	Willowbrook Visiting Nurse Association							x		x		x				x				x	x		6
79246	Shelby	215	Amedisys Home Health Care							x												x	x		3
79256	Shelby	216	Americare Home Health Agency, Inc																			x	x		2
79276	Shelby	241	Baptist Trinity Home Care				x		x	x		x		x				x				x	x		8
79316	Shelby	233	Methodist Alliance Home Care						x	x		x		x				x				x	x		7
79376	Shelby	240	Homechoice Health Services							x		x		x				x				x	x		6
79386	Shelby	238	Amedisys Tennessee, LLC							x								x				x	x		4
79446	Shelby	242	Baptist Trinity Home Care - Private Pay							x		x		x								x	x		5
79456	Shelby	347	Accredo Health Group, Inc							x		x		x				x				x	x		6
79466	Shelby	459	Alere Women's and Children's Health LLC	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
79486	Shelby	227	Home Health Care of West Tennessee, Inc							x								x				x	x		4
79496	Shelby	610	Functional Independence Home Care, Inc							x												x	x		3
79506	Shelby	611	No Place Like Home, Inc							x												x	x		3
79526	Shelby	616	Still Waters Home Health Agency																			x			1
79536	Shelby	618	Maxim Healthcare Services, Inc.							x		x		x					x			x	x		6
79546	Shelby	621	Best Nurses, Inc.							x												x	x		3
79556	Shelby	120	Coram CVS/Specialty Infusion Service	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	21
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis																						
92025	Weakley	276	Careall Homecare Services	x	x		x		x		x					x	x		x		x	X		x	10
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice									x								x					2
96020	Fulton Co., KY	297	Regional Home Care Parkway																					x	1
			Agencies Availablee to Each County	18	18	17	17	19	16	29	19	22	19	21	17	17	10	19	21	19	15	28	28	20	

Note: Hemophilia Preferred Care of West Tennessee licensed 7/15 but not yet assigned a State ID as of 6-10-16.

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)

Table Seven-A: Patients Served in 2015 by Agencies in The Project's Proposed Service Area--BY AGENCY NAME

Health Statistics ID	Agency County	License Number	Agency	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Total
79456	Shelby	347	Accredo Health Group, Inc						1								1				21				23
79466	Shelby	459	Alere Women's and Children's Health LLC						8		6		2				6	28			332	19			401
79146	Shelby	239	Amedisys Home Care						1												947				948
33103	Hamilton	113	Amedisys Home Health																						0
57075	Madison	177	Amedisys Home Health Care	105	74	32	140	24	294	x	172	78	197	52	21	363		253	409	117	273			98	2,702
79246	Shelby	215	Amedisys Home Health Care						51												686	0			737
79386	Shelby	238	Amedisys Tennessee, LLC						4				1								140	409			554
79256	Shelby	216	Americare Home Health Agency, Inc																		807	21			828
09065	Carroll	19	Baptist Memorial Home Care & Hospice	15	207	1		1		11				8	1			11						2	257
79276	Shelby	241	Baptist Trinity Home Care						155												2,871	143			3,169
79446	Shelby	242	Baptist Trinity Home Care - Private Pay																		1				1
79546	Shelby	621	Best Nurses, Inc.																		9				9
38015	Haywood	288	Careall Homecare Services			50	62	2	5	3	51	71	8	109	49			155	125	19			74		783
60074	Maury	194	Careall Homecare Services					7					107							14					128
92025	Weakley	276	Careall Homecare Services	26	97		2		100		145					47	74				308			484	1,283
79556	Shelby	120	Coram CVS/Specialty Infusion Service						1												3				4
36025	Hardin	290	Deaconess Homecare			57		20				55	280		33				24	257					726
19494	Davidson	42	Elk Valley Health Services Inc	4	7		4	1	6		14	2	17	5	4	8	1	1	7	2	12	19	1	3	118
57095	Madison	120	Extendicare Home Health of West Tennessee	61	76	16	71	7	155	5	33	8	1	9	5	77	9	120	147	16		338	40	2	1,196
66035	Obion	188	Extendicare Home Health of Western Tennessee								9						46				219			46	320
79206	Shelby	229	Family Home Health Agency																			504			504
79496	Shelby	610	Functional Independence Home Care, Inc						70													1,775	70		1,915
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)			1							250							76					327
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis (NR)																						
40075	Henry	122	Henry County Medical Center Home Health	53	35											319								11	418
19544	Davidson	56	Home Care Solutions, Inc																						0
79486	Shelby	227	Home Health Care of West Tennessee, Inc						23									25				468	61		577
79376	Shelby	240	Homechoice Health Services						60		155		175					101				977	57		1,525
79226	Shelby	214	Intrepid USA Healthcare Services																			565			565
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)		13	28	28	7		11	77	10	15	52	103			10	131	16			28	3	532
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice										12							48					60
79536	Shelby	618	Maxim Healthcare Services, Inc.						4			17		11					74			162	7		275
57055	Madison	174	Medical Center Home Health		28	65	58	15	8		350	194	22	70	83				588	52				6	1,539
79106	Shelby	237	Meritan, Inc.																			652			652
79316	Shelby	233	Methodist Alliance Home Care						45													2,952	181		3,178
24026	Fayette	291	NHC Homecare						148		69		19					1		6		171	7		421
27025	Gibson	85	NHC Homecare	34	64	8	16	9	6		279				20	27			164		10			29	666
60024	Maury	181	NHC Homecare																						0
79506	Shelby	611	No Place Like Home, Inc																			79	1		80
79136	Shelby	224	Quality Home Health Svc (Extended Hlth Care)						3													284	4		291
23035	Dyer	77	Regional Home Care - Dyersburg				30		865		49						137	225			25				1,331
57085	Madison	178	Regional Home Care - Jackson		7	52	63	1		13	190	81	39	140				9	523	217	126		14	330	1,805
39035	Henderson	139	Regional Home Care - Lexington	25	482	14		45					11		481	77			9					19	1,163
96020	Fulton Co., KY	297	Regional Home Care Parkway																		42			6	48
41034	Hickman	125	St. Thomas Home Health	1																					1
79526	Shelby	616	Still Waters Home Health Agency																			58			58
03025	Benton	8	Tennessee Quality Homecare - Northwest	145	101			1		65						155			1		68			93	629
20045	Decatur	221	Tennessee Quality Homecare - Southwest			119		92					66		78				260	85					700
27085	Gibson	285	Volunteer Home Care, Inc	215	274		93		463		425						196		717		231			71	2,685
20055	Decatur	63	Volunteer Homecare of West Tennessee			102		416				157	75		324				2	213					1,289
24036	Fayette	612	Where The Heart Is						13													1,015	16		1,044
79236	Shelby	244	Willowbrook Visiting Nurse Association						88			17		4								433	19		561
			TOTAL PATIENTS BY COUNTY	**684**	**1,465**	**545**	**567**	**648**	**1,902**	**707**	**1,870**	**920**	**1,100**	**649**	**1,209**	**1,074**	**463**	**907**	**3,220**	**1,138**	**1,314**	**16,269**	**1,172**	**1,203**	**39,026**

Total Number of Licensed Agencies--52

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)
Note: Hemophilia Preferred Care was licensed in 7/15 and has not filed a 2015 Joint Annual Report.

Table Seven-B: Patients Served in 2015 by Agencies in the Project's Proposed Service Area--BY AGENCY ID NUMBER

Health Statistics ID	Agency County	License Number	Agency	Benton	Carroll	Chester	Crockett	Decatur	Dyer	Fayette	Gibson	Hardeman	Hardin	Haywood	Henderson	Henry	Lake	Lauderdale	Madison	McNairy	Obion	Shelby	Tipton	Weakley	Total
03025	Benton	8	Tennessee Quality Homecare - Northwest	145	101			1			65					155			1		68			93	629
09065	Carroll	19	Baptist Memorial Home Care & Hospice	15	207	1		1			11				8	1			11					2	257
19494	Davidson	42	Elk Valley Health Services Inc	4	7		4	1	6		14	2	17	5	4	8	1	1	7	2	12	19	1	3	118
19544	Davidson	56	Home Care Solutions, Inc																						0
20045	Decatur	221	Tennessee Quality Homecare - Southwest			119		92					66		78				260	85					700
20055	Decatur	63	Volunteer Homecare of West Tennessee			102		416				157	75		324				2	213					1,289
23035	Dyer	77	Regional Home Care - Dyersburg				30		865		49						137	225			25				1,331
24026	Fayette	291	NHC Homecare							148		69		19				1		6		171	7		421
24036	Fayette	612	Where The Heart Is							13												1,015	16		1,044
27025	Gibson	85	NHC Homecare	34	64	8	16	9	6		279				20	27			164		10			29	666
27085	Gibson	285	Volunteer Home Care, Inc	215	274		93		463		425						196		717		231			71	2,685
33103	Hamilton	113	Amedisys Home Health																						0
36025	Hardin	290	Deaconess Homecare			57		20				55	280		33				24	257					726
36035	Hardin	137	Hardin Medical Center Home Health (HMC HH)			1							250							76					327
38015	Haywood	288	Careall Homecare Services			50	62	2	5	3	51	71	8	109	49			155	125	19			74		783
39035	Henderson	139	Regional Home Care - Lexington	25	482	14		45					11		481	77			9					19	1,163
40075	Henry	122	Henry County Medical Center Home Health	53	35											319								11	418
41034	Hickman	125	St. Thomas Home Health	1																					1
57055	Madison	174	Medical Center Home Health		28	65	58	15	8		350	194	22	70	83				588	52				6	1,539
57075	Madison	177	Amedisys Home Health Care	105	74	32	140	24	294	x	172	78	197	52	21	363		253	409	117	273			98	2,702
57085	Madison	178	Regional Home Care - Jackson		7	52	63	1		13	190	81	39	140				9	523	217	126		14	330	1,805
57095	Madison	120	Extendicare Home Health of West Tennessee	61	76	16	71	7	155	5	33	8	1	9	5	77	9	120	147	16		338	40	2	1,196
57165	Madison	175	Intrepid USA Healthcare Services (F.C. of TN)		13	28	28	7		11	77	10	15	52	103			10	131	16			28	3	532
60024	Maury	181	NHC Homecare																						0
60074	Maury	194	Careall Homecare Services					7					107							14					128
66035	Obion	188	Extendicare Home Health of Western Tennessee								9						46				219			46	320
79106	Shelby	237	Meritan, Inc.																			652			652
79136	Shelby	224	Quality Home Health Svc (Extended Hlth Care)							3												284	4		291
79146	Shelby	239	Amedisys Home Care							1												947			948
79206	Shelby	229	Family Home Health Agency																			504			504
79226	Shelby	214	Intrepid USA Healthcare Services																			565			565
79236	Shelby	244	Willowbrook Visiting Nurse Association							88		17		4								433	19		561
79246	Shelby	215	Amedisys Home Health Care							51												686	0		737
79256	Shelby	216	Americare Home Health Agency, Inc																			807	21		828
79276	Shelby	241	Baptist Trinity Home Care							155												2,871	143		3,169
79316	Shelby	233	Methodist Alliance Home Care							45												2,952	181		3,178
79376	Shelby	240	Homechoice Health Services							60		155		175				101				977	57		1,525
79386	Shelby	238	Amedisys Tennessee, LLC							4				1								140	409		554
79446	Shelby	242	Baptist Trinity Home Care - Private Pay																			1			1
79456	Shelby	347	Accredo Health Group, Inc							1								1				21			23
79466	Shelby	459	Alere Women's and Children's Health LLC							8		6		2				6	28			332	19		401
79486	Shelby	227	Home Health Care of West Tennessee, Inc							23								25				468	61		577
79496	Shelby	610	Functional Independence Home Care, Inc							70												1,775	70		1,915
79506	Shelby	611	No Place Like Home, Inc																			79	1		80
79526	Shelby	616	Still Waters Home Health Agency																			58			58
79536	Shelby	618	Maxim Healthcare Services, Inc.							4		17		11					74			162	7		275
79546	Shelby	621	Best Nurses, Inc.																			9			9
79556	Shelby	120	Coram CVS/Specialty Infusion Service							1												3			4
unassign.	Shelby	625	Hemophilia Preferred Care of Memphis																						1
92025	Weakley	276	Careall Homecare Services	26	97		2		100		145					47	74				308			484	1,283
96010	Alcorn Co, MS	296	Magnolia Regional Health Care Home Hospice										12							48					60
96020	Fulton Co., KY	297	Regional Home Care Parkway																		42			6	48
			TOTAL PATIENTS BY COUNTY	684	1,465	545	567	648	1,902	707	1,870	920	1,100	649	1,209	1,074	463	907	3,220	1,138	1,314	16,269	1,172	1,203	39,026

Total Number of Licensed Agencies--52

Source: Department of Health Licensure - 10/7/2015 (Updated 2/2/2016)
Note: Hemophilia Preferred Care wdas licensed in 7/16 and has not yet filed a 2015 Joint Annual Report.

Table Eight-A: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY NAME

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
		AREAWIDE TOTALS AND AVERAGES			**47,730**	**49,917**	**50,652**	**39,026**	**77.0%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.
Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.
Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

Table Eight-B: Patients Served by Home Health Agencies 2013-2015 in the Project's Proposed Service Area BY AGENCY ID

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
		AREAWIDE TOTALS AND AVERAGES			**47,730**	**49,917**	**50,652**	**39,026**	**77.0%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.
Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.
Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

Table Eight-C: Patients Served 2013-2015 by Home Health Agencies in the Project's Proposed Service Area RANKED BY RELIANCE ON PROPOSED SERVICE AREA

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2013 JAR Total Patients Served in TN	2014 JAR Total Patients Served in TN	2015 JAR Total Patients Served in TN	2015 Total Patients Served in Axelacare's Proposed Service Area	2015 Total Patients Served in Axelacare's Proposed Service Area as Percent of Agency's Total TN Patients
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	707	1,452	1,331	1,331	100.0%
24026	Fayette	NHC Homecare	291	6/6/83	226	301	421	421	100.0%
24036	Fayette	Where the Heart Is	612	8/10/05	116	104	1,044	1,044	100.0%
27025	Gibson	NHC Homecare	85	2/7/77	569	655	666	666	100.0%
57055	Madison	Medical Center Home Health	174	7/1/76	1,706	1,098	1,539	1,539	100.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	2,741	2,541	2,702	2,702	100.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	1,164	1,863	1,805	1,805	100.0%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	1,085	832	1,196	1,196	100.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	302	119	320	320	100.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	609	632	652	652	100.0%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	79	204	291	291	100.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	1,060	1,070	948	948	100.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	379	428	504	504	100.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	605	522	565	565	100.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	479	499	561	561	100.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	936	837	737	737	100.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	1,811	1,295	828	828	100.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	3,862	3,236	3,169	3,169	100.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	1,934	1,856	554	554	100.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	1	1	1	1	100.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	20	21	23	23	100.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	1,010	754	577	577	100.0%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	953	1,494	1,915	1,915	100.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	58	80	80	80	100.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	101	71	58	58	100.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	155	173	275	275	100.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	364	176	9	9	100.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84			4	4	100.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	43	35	60	60	100.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	28	39	48	48	100.0%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	569	582	1,164	1,163	99.9%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	422	507	533	532	99.8%
38015	Haywood	Careall Homecare Services	288	6/7/84			786	783	99.6%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	262	283	263	257	97.7%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	363	408	428	418	97.7%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	3,041	2,995	2,842	2,685	94.5%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	341	205	348	327	94.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	2,036	2,337	1,368	1,283	93.8%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	2,935	3,149	3,469	3,178	91.6%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	373	335	438	401	91.6%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	1,534	1,794	1,833	1,289	70.3%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	1,080	988	1,043	700	67.1%
36025	Hardin	Deaconess Homecare	290	2/11/83	1,330	2,122	1,120	726	64.8%
79376	Shelby	Homechoice Health Services	240	3/5/84	861	2,322	2,372	1,525	64.3%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	1,164	1,173	1,381	629	45.5%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	277	293	457	118	25.8%
60074	Maury	Careall Homecare Services	194	2/9/84	609	881	614	128	20.8%
41034	Hickman	St. Thomas Home Health	125	6/1/84	214	311	370	1	0.3%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	1,930	1,689	1,813	0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	2,878	2,564	2,610	0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	2,408	2,591	2,517	0	0.0%
		AREAWIDE TOTALS AND AVERAGES			**47,730**	**49,917**	**50,652**	**39,026**	**77.0%**

Source: TDH; 2013-2015 Joint Annual Reports of Home Health Agencies

Notes: Hemophilia Preferred Care is omitted because it was not licensed until 7-15 and has not filed a 2015 Joint Annual Report.
Regional Home Care Parkway was licensed to serve Obion & Weakley Counties, but has now withdrawn from further service in TN.
Magnolia Regional Health Care Home Hospice totals include only TN patients. All others served are located out-of-state.

Table Nine-A: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area BY AGENCY NAME							
Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	$0	$0	0.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	$532,931	$187,059	35.1%
79146	Shelby	Amedisys Home Care	239	6/3/82	$3,379,165	$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	$11,268,119	$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	$2,560,156	$0	0.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	$5,994,682	$0	0.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	$4,597,317	$82,434	1.8%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	$851,909	$0	0.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	$8,819,896	$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	$105,992	$0	0.0%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	$587,773	$34,944	5.9%
38015	Haywood	Careall Homecare Services	288	6/7/84	$9,728,281	$7,188,871	73.9%
60074	Maury	Careall Homecare Services	194	2/9/84	$2,046,573	$691,843	33.8%
92025	Weakley	Careall Homecare Services	276	6/16/83	$9,728,043	$4,694,898	48.3%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	$44,285	$0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	$5,199,674	$56,683	1.1%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	$31,824,839	$22,851,469	71.8%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	$5,039,289	$0	0.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	$1,059,757	$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	$2,787,546	$0	0.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	$2,429,693	$708,945	29.2%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	$16,088,606	$12,524,168	77.8%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	$1,490,082	$0	0.0%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	$1,084,043	$24,273	2.2%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	$9,626,513	$0	0.0%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	$13,455,448	$9,408,321	69.9%
79376	Shelby	Homechoice Health Services	240	3/5/84	$9,939,690	$3,110,466	31.3%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	$2,631,668	$0	0.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	$1,911,049	$0	0.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	$12,648,142	$11,875,369	93.9%
57055	Madison	Medical Center Home Health	174	7/1/76	$4,852,062	$0	0.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	$2,517,728	$361,846	14.4%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	$7,676,244	$92,400	1.2%
24026	Fayette	NHC Homecare	291	6/6/83	$2,280,789	$0	0.0%
27025	Gibson	NHC Homecare	85	2/7/77	$3,599,719	$0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	$12,903,737	$0	0.0%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	$14,336,680	$13,511,680	94.2%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	$4,946,049	$3,748,824	75.8%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	$3,388,915	$79,413	2.3%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	$1,699,355	$7,603	0.4%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	$2,824,090	$44,014	1.6%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	$140,175	$0	0.0%
41034	Hickman	St. Thomas Home Health	125	6/1/84	$1,017,852	$116,400	11.4%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	$410,000	$0	0.0%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	$6,359,471	$289,696	4.6%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	$5,030,388	$765,288	15.2%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	$15,150,499	$3,673,507	24.2%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	$11,690,520	$4,028,254	34.5%
24036	Fayette	Where the Heart Is	612	8/10/05	$2,344,460	$250,218	10.7%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	$1,473,079	$0	0.0%
		AREAWIDE TOTALS AND AVERAGES			**$291,763,488**	**$100,408,886**	**34.4%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

Table Nine-B: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Primary Service Area BY AGENCY ID NUMBER							
Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	$6,359,471	$289,696	4.6%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	$851,909	$0	0.0%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	$31,824,839	$22,851,469	71.8%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	$9,626,513	$0	0.0%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	$5,030,388	$765,288	15.2%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	$11,690,520	$4,028,254	34.5%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	$3,388,915	$79,413	2.3%
24026	Fayette	NHC Homecare	291	6/6/83	$2,280,789	$0	0.0%
24036	Fayette	Where the Heart Is	612	8/10/05	$2,344,460	$250,218	10.7%
27025	Gibson	NHC Homecare	85	2/7/77	$3,599,719	$0	0.0%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	$15,150,499	$3,673,507	24.2%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
36025	Hardin	Deaconess Homecare	290	2/11/83	$5,199,674	$56,683	1.1%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	$1,490,082	$0	0.0%
38015	Haywood	Careall Homecare Services	288	6/7/84	$9,728,281	$7,188,871	73.9%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	$2,824,090	$44,014	1.6%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	$1,084,043	$24,273	2.2%
41034	Hickman	St. Thomas Home Health	125	6/1/84	$1,017,852	$116,400	11.4%
57055	Madison	Medical Center Home Health	174	7/1/76	$4,852,062	$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	$11,268,119	$0	0.0%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	$1,699,355	$7,603	0.4%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	$5,039,289	$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	$2,787,546	$0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	$12,903,737	$0	0.0%
60074	Maury	Careall Homecare Services	194	2/9/84	$2,046,573	$691,843	33.8%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	$1,059,757	$0	0.0%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	$2,517,728	$361,846	14.4%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	$4,946,049	$3,748,824	75.8%
79146	Shelby	Amedisys Home Care	239	6/3/82	$3,379,165	$0	0.0%
79206	Shelby	Family Home Health Agency	229	3/10/77	$2,429,693	$708,945	29.2%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	$2,631,668	$0	0.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	$1,473,079	$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	$2,560,156	$0	0.0%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	$4,597,317	$82,434	1.8%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	$8,819,896	$0	0.0%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	$7,676,244	$92,400	1.2%
79376	Shelby	Homechoice Health Services	240	3/5/84	$9,939,690	$3,110,466	31.3%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	$5,994,682	$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	$105,992	$0	0.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	$0	$0	0.0%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	$532,931	$187,059	35.1%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	$13,455,448	$9,408,321	69.9%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	$16,088,606	$12,524,168	77.8%
79506	Shelby	No Place Like Home, Inc	611	7/1/05	$14,336,680	$13,511,680	94.2%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	$410,000	$0	0.0%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	$12,648,142	$11,875,369	93.9%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	$587,773	$34,944	5.9%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	$44,285	$0	0.0%
92025	Weakley	Careall Homecare Services	276	6/16/83	$9,728,043	$4,694,898	48.3%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	$1,911,049	$0	0.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	$140,175	$0	0.0%
		AREAWIDE TOTALS AND AVERAGES			**$291,763,488**	**$100,408,886**	**34.4%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

Table Nine-C: 2015 TennCare Payor Mix of Home Health Agencies in the Project's Proposed Service Area
RANKED BY TENNCARE PERCENT OF TOTAL AGENCY GROSS CHARGES

Health Statistics ID Number	County of Parent Office	Home Health Agency Name	Agency License Number	Date Agency Licensed	2015 Total Gross Revenues	2015 TennCare Gross Revenues	2015 TennCare Percent of Total Gross Revenues
79506	Shelby	No Place Like Home, Inc	611	7/1/05	$14,336,680	$13,511,680	94.2%
79536	Shelby	Maxim Healthcare Services, Inc.	618	10/9/07	$12,648,142	$11,875,369	93.9%
79496	Shelby	Functional Independence Home Care, Inc	610	8/13/04	$16,088,606	$12,524,168	77.8%
79136	Shelby	Quality Home Health Svc (Elder Care/Extended HC)	224	12/3/81	$4,946,049	$3,748,824	75.8%
38015	Haywood	Careall Homecare Services	288	6/7/84	$9,728,281	$7,188,871	73.9%
19494	Davidson	Elk Valley Health Services Inc	42	7/17/84	$31,824,839	$22,851,469	71.8%
79486	Shelby	Home Health Care of West Tennessee, Inc	227	5/2/84	$13,455,448	$9,408,321	69.9%
92025	Weakley	Careall Homecare Services	276	6/16/83	$9,728,043	$4,694,898	48.3%
79466	Shelby	Alere Women's and Children's Health LLC	459	12/21/98	$532,931	$187,059	35.1%
20055	Decatur	Volunteer Homecare of West Tennessee	63	6/11/84	$11,690,520	$4,028,254	34.5%
60074	Maury	Careall Homecare Services	194	2/9/84	$2,046,573	$691,843	33.8%
79376	Shelby	Homechoice Health Services	240	3/5/84	$9,939,690	$3,110,466	31.3%
79206	Shelby	Family Home Health Agency	229	3/10/77	$2,429,693	$708,945	29.2%
27085	Gibson	Volunteer Home Care, Inc	285	5/26/82	$15,150,499	$3,673,507	24.2%
20045	Decatur	Tennessee Quality Homecare - Southwest	221	3/19/84	$5,030,388	$765,288	15.2%
79106	Shelby	Meritan, Inc. (Senior Services Home Health)	237	7/25/77	$2,517,728	$361,846	14.4%
41034	Hickman	St. Thomas Home Health	125	6/1/84	$1,017,852	$116,400	11.4%
24036	Fayette	Where the Heart Is	612	8/10/05	$2,344,460	$250,218	10.7%
79546	Shelby	Best Nurses, Inc.	621	7/1/08	$587,773	$34,944	5.9%
03025	Benton	Tennessee Quality Homecare - Northwest	8	3/14/83	$6,359,471	$289,696	4.6%
23035	Dyer	Regional Home Care - Dyersburg	77	2/18/84	$3,388,915	$79,413	2.3%
40075	Henry	Henry County Medical Center Home Health	122	12/7/84	$1,084,043	$24,273	2.2%
79256	Shelby	Americare Home Health Agency, Inc	216	1/24/84	$4,597,317	$82,434	1.8%
39035	Henderson	Regional Home Care - Lexington	139	2/1/84	$2,824,090	$44,014	1.6%
79316	Shelby	Methodist Alliance Home Care	233	7/1/88	$7,676,244	$92,400	1.2%
36025	Hardin	Deaconess Homecare	290	2/11/83	$5,199,674	$56,683	1.1%
57085	Madison	Regional Home Care - Jackson	178	6/7/84	$1,699,355	$7,603	0.4%
09065	Carroll	Baptist Memorial Home Care & Hospice	19	7/3/84	$851,909	$0	0.0%
19544	Davidson	Home Care Solutions, Inc (LHC HomeCare of TN)	56	9/7/88	$9,626,513	$0	0.0%
24026	Fayette	NHC Homecare	291	6/6/83	$2,280,789	$0	0.0%
27025	Gibson	NHC Homecare	85	2/7/77	$3,599,719	$0	0.0%
33103	Hamilton	Amedisys Home Health	113	7/1/81	$9,660,515	$0	0.0%
36035	Hardin	Hardin Medical Center Home Health	137	12/20/93	$1,490,082	$0	0.0%
57055	Madison	Medical Center Home Health	174	7/1/76	$4,852,062	$0	0.0%
57075	Madison	Amedisys Home Health Care	177	5/2/84	$11,268,119	$0	0.0%
57095	Madison	Extendicare Home Health of West Tennessee	120	6/18/84	$5,039,289	$0	0.0%
57165	Madison	F. C. of Tennessee, Inc. (Intrepid)	175	9/26/84	$2,787,546	$0	0.0%
60024	Maury	NHC Homecare	181	11/22/77	$12,903,737	$0	0.0%
66035	Obion	Extendicare Home Health of Western Tennessee	188	5/3/84	$1,059,757	$0	0.0%
79146	Shelby	Amedisys Home Care	239	6/3/82	$3,379,165	$0	0.0%
79226	Shelby	Intrepid USA Healthcare Services	214	8/25/83	$2,631,668	$0	0.0%
79236	Shelby	Willowbrook Visiting Nurse Association	244	5/12/76	$1,473,079	$0	0.0%
79246	Shelby	Amedisys Home Health Care	215	4/24/84	$2,560,156	$0	0.0%
79276	Shelby	Baptist Trinity Home Care	241	6/26/84	$8,819,896	$0	0.0%
79386	Shelby	Amedisys Tennessee, LLC (Amedisys Home Health)	238	2/29/84	$5,994,682	$0	0.0%
79446	Shelby	Baptist Trinity Home Care - Private Pay	242	9/6/83	$105,992	$0	0.0%
79456	Shelby	Accredo Health Group, Inc	347	5/9/97	$0	$0	0.0%
79526	Shelby	Still Waters Home Health Agency	616	7/1/06	$410,000	$0	0.0%
79556	Shelby	Coram/CVS Specialty Infusion Service	120	6/18/84	$44,285	$0	0.0%
96010	Alcorn Co, MS	Magnolia Regional Health Care Home Hospice	296	3/24/82	$1,911,049	$0	0.0%
96020	Fulton Co, KY	Regional Home Care Parkway	297	2/18/84	$140,175	$0	0.0%
		AREAWIDE TOTALS AND AVERAGES			**$291,763,488**	**$100,408,886**	**34.4%**

Source: TDH; 2015 Joint Annual Reports of Home Health Agencies

Note: Hemophilia Preferred Care is omitted because it was not operational in this period.

C(I).6. PROVIDE APPLICABLE UTILIZATION AND/OR OCCUPANCY STATISTICS FOR YOUR INSTITUTION FOR EACH OF THE PAST THREE (3) YEARS AND THE PROJECTED ANNUAL UTILIZATION FOR EACH OF THE TWO (2) YEARS FOLLOWING COMPLETION OF THE PROJECT. ADDITIONALLY, PROVIDE THE DETAILS REGARDING THE METHODOLOGY USED TO PROJECT UTILIZATION. THE METHODOLOGY MUST INCLUDE DETAILED CALCULATIONS OR DOCUMENTATION FROM REFERRAL SOURCES, AND IDENTIFICATION OF ALL ASSUMPTIONS.

Table Ten below shows AxelaCare management's projected utilization in Years One and Two. Patients were projected by reviewing Tennessee referrals. That was increased to reflect the growth expected when physicians learn that AlexaCare has been authorized to rapidly provide well-equipped and highly competent nursing and pharmacy teams, as well as medications, to serve immune-compromised patients at any location in West Tennessee.

Table Ten: Projected Utilization of AxelaCare Healthcare Solutions CY2017 - CY2018

	CY2017	CY2018
Patients	45	65
Visits	1,080	1,560

The number of visits required to serve immune globulin infusion patients vary widely, depending on the physician's direction as to dosage amount, rate of infusion, spacing of infusions (daily, alternating days, weekly, etc.) and duration of treatment. For CON purposes, AxelaCare used an average of 24 visits per patient per year.

C(II)1. PROVIDE THE COST OF THE PROJECT BY COMPLETING THE PROJECT COSTS CHART ON THE FOLLOWING PAGE. JUSTIFY THE COST OF THE PROJECT.

• ALL PROJECTS SHOULD HAVE A PROJECT COST OF AT LEAST $3,000 ON LINE F (MINIMUM CON FILING FEE). CON FILING FEE SHOULD BE CALCULATED ON LINE D.

• THE COST OF ANY LEASE (BUILDING, LAND, AND/OR EQUIPMENT) SHOULD BE BASED ON FAIR MARKET VALUE OR THE TOTAL AMOUNT OF THE LEASE PAYMENTS OVER THE INITIAL TERM OF THE LEASE, WHICHEVER IS GREATER. NOTE: THIS APPLIES TO ALL EQUIPMENT LEASES INCLUDING BY PROCEDURE OR "PER CLICK" ARRANGEMENTS. THE METHODOLOGY USED TO DETERMINE THE TOTAL LEASE COST FOR A "PER CLICK" ARRANGEMENT MUST INCLUDE, AT A MINIMUM, THE PROJECTED PROCEDURES, THE "PER CLICK" RATE AND THE TERM OF THE LEASE.

• THE COST FOR FIXED AND MOVEABLE EQUIPMENT INCLUDES, BUT IS NOT NECESSARILY LIMITED TO, MAINTENANCE AGREEMENTS COVERING THE EXPECTED USEFUL LIFE OF THE EQUIPMENT; FEDERAL, STATE, AND LOCAL TAXES AND OTHER GOVERNMENT ASSESSMENTS; AND INSTALLATION CHARGES, EXCLUDING CAPITAL EXPENDITURES FOR PHYSICAL PLANT RENOVATION OR IN-WALL SHIELDING, WHICH SHOULD BE INCLUDED UNDER CONSTRUCTION COSTS OR INCORPORATED IN A FACILITY LEASE.

• FOR PROJECTS THAT INCLUDE NEW CONSTRUCTION, MODIFICATION, AND/OR RENOVATION; DOCUMENTATION MUST BE PROVIDED FROM A CONTRACTOR AND/OR ARCHITECT THAT SUPPORT THE ESTIMATED CONSTRUCTION COSTS.

Licensure of the project will require AxelaCare to establish a home office in the agency's service area. The leased space will consist of one 149-SF office in an Executive Suite on that floor. It requires no new construction, modification or renovation. The only actual capital cost of the project other than the CON filing fee of $3000 will be a minimal expense for office furnishings and equipment for one nurse manager (line A8) and legal and consulting fees (line A2). The latter estimate includes a contingency for legal expenses in the event the project is opposed.

Line B.1 is the fair market value of the facility being leased, calculated in the two alternative ways required by CON staff rules. The lease outlay was the larger of these two alternative calculations and was used in the Project Cost Chart.

Alternative Calculations

1. *Lease Outlay Method*

1 year first lease term X $969 per month = **$11,628 outlay in first term**

2. *Pro Rata Fair Market Value Method*

Value of land and building (current appraisal):	$22,010,300 (See Attachments)
SF of building:	1,172,656 SF (See Attachments)
Area of leased space for this project:	149 SF (see lease document)
Calculation of FMV of space:	149 SF / 1,172,656 SF X $22,010,300 = **$2,797 FMV of leased space**

PROJECT COSTS CHART--AXELACARE WEST TENNESSEE

V.1--4/12/16

A. Construction and equipment acquired by purchase:

1.	Architectural and Engineering Fees	$ 0
2.	Legal, Administrative, Consultant Fees (Excl CON Filing Fee)	50,000
3.	Acquisition of Site	0
4.	Preparation of Site	0
5.	Construction Cost	0
6.	Contingency Fund	0
7.	Fixed Equipment (Not included in Construction Contract)	0
8.	Moveable Equipment (List all equipment over $50,000)	5,000
9.	Other (Specify) _____	0

B. Acquisition by gift, donation, or lease:

1.	Facility (inclusive of building and land)	Lease Outlay	11,628
2.	Building only		0
3.	Land only		0
4.	Equipment (Specify) _____		0
5.	Other (Specify) _____		0

C. Financing Costs and Fees:

1.	Interim Financing	0
2.	Underwriting Costs	0
3.	Reserve for One Year's Debt Service	0
4.	Other (Specify) _____	0

D. Estimated Project Cost (A+B+C) 66,628

E. CON Filing Fee 3,000

F. Total Estimated Project Cost (D+E) **TOTAL $** 69,628

Actual Capital Cost 58,000
Section B FMV 11,628

C(II).2. IDENTIFY THE FUNDING SOURCES FOR THIS PROJECT.

a. PLEASE CHECK THE APPLICABLE ITEM(S) BELOW AND BRIEFLY SUMMARIZE HOW THE PROJECT WILL BE FINANCED. (DOCUMENTATION FOR THE TYPE OF FUNDING MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND IDENTIFIED AS ATTACHMENT C, ECONOMIC FEASIBILITY--2).

_____A. Commercial Loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;

_____B. Tax-Exempt Bonds--copy of preliminary resolution or a letter from the issuing authority, stating favorable contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;

_____C. General Obligation Bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting;

_____D. Grants--Notification of Intent form for grant application or notice of grant award;

__x__E. Cash Reserves--Appropriate documentation from Chief Financial Officer; or

_____F. Other--Identify and document funding from all sources.

The project will be funded/financed by the applicant's parent company. Documentation of financing is provided in Attachment C, Economic Feasibility--2.

C(II).3. DISCUSS AND DOCUMENT THE REASONABLENESS OF THE PROPOSED PROJECT COSTS. IF APPLICABLE, COMPARE THE COST PER SQUARE FOOT OF CONSTRUCTION TO SIMILAR PROJECTS RECENTLY APPROVED BY THE HSDA.

Not applicable because the project does not require any kind of construction.

C(II).4. COMPLETE HISTORICAL AND PROJECTED DATA CHARTS ON THE FOLLOWING TWO PAGES--DO NOT MODIFY THE CHARTS PROVIDED OR SUBMIT CHART SUBSTITUTIONS. HISTORICAL DATA CHART REPRESENTS REVENUE AND EXPENSE INFORMATION FOR THE LAST THREE (3) YEARS FOR WHICH COMPLETE DATA IS AVAILABLE FOR THE INSTITUTION. PROJECTED DATA CHART REQUESTS INFORMATION FOR THE TWO YEARS FOLLOWING COMPLETION OF THIS PROPOSAL. PROJECTED DATA CHART SHOULD INCLUDE REVENUE AND EXPENSE PROJECTIONS FOR THE PROPOSAL ONLY (I.E., IF THE APPLICATION IS FOR ADDITIONAL BEDS, INCLUDE ANTICIPATED REVENUE FROM THE PROPOSED BEDS ONLY, NOT FROM ALL BEDS IN THE FACILITY).

See the following pages for these charts, with notes where applicable. The applicant is not operational; so no Historic Data Chart is required.

Three Projected Data Charts have been submitted to provide clarification of how the project is financially feasible. One chart is for the proposed home nursing operation itself. The second chart is only for the AxelaCare operation in Lenexa, Kansas, that will support the nursing service by supplying pharmaceutical products to be infused. The third is the consolidated chart that reflects the full business income and expenses involved in offering an integrated program.

The AxelaCare home health nursing service that is proposed in this application will operate at a financial loss. But, the Kansas-based specialty pharmacy supporting the service is already licensed and operating throughout Tennessee, and it will be profitable enough to absorb those losses. There will be a positive margin when the two components of the operation are viewed in combination.

This is analogous to a project to expand a hospital emergency room: the expansion or the emergency room may operate at a loss when viewed in isolation. However, its losses will be absorbed into the overall hospital operation, which will show a positive operating margin with the new project open.

SUPPLEMENTAL #1

PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE 24, 2016
NURSING AND HOME OFFICE ONLY--PHARMACEUTICALS EXCLUDED

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

			CY 2017	CY 2018
		PATIENTS	45	65
A.	Utilization Data	VISITS	1,080	1,560
B.	Revenue from Services to Patients			
	1. Inpatient Services		$	$
	2. Outpatient Services-home health nursing visits		259,200	374,400
	3. Emergency Services			
	4. Other Operating Revenue (Specify) See notes page			
		Gross Operating Revenue	$ 259,200	$ 374,400
C.	Deductions for Operating Revenue			
	1. Contractual Adjustments		$	$
	2. Provision for Charity Care		5,184	7,488
	3. Provisions for Bad Debt		2,592	3,744
		Total Deductions	$ 7,776	$ 11,232
NET OPERATING REVENUE			$ 251,424	$ 363,168
D.	Operating Expenses			
	1. Salaries and Wages		$ 369,840	$ 483,605
	2. Physicians Salaries and Wages			
	3. Supplies		12,571	18,158
	4. Taxes			
	5. Depreciation			
	6. Rent		11,628	12,209
	7. Interest, other than Capital			
	8. Management Fees			
	a. Fees to Affiliates			
	b. Fees to Non-Affiliates			
	9. Other Expenses (Specify) See notes page		7,798	19,783
		Total Operating Expenses	$ 401,837	$ 533,755
E.	Other Revenue (Expenses) -- Net (Specify)		$	$
NET OPERATING INCOME (LOSS)			$ (150,413)	$ (170,587)
F.	Capital Expenditures			
	1. Retirement of Principal		$	$
	2. Interest			
		Total Capital Expenditures	$ 0	$ 0
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$ (150,413)	$ (170,587)

SUPPLEMENTAL #1

June 23, 2016

12:14 pm

PROJECTED DATA CHART-- AXELACARE WEST TENNESSEE PHARMACEUTICALS ONLY (FROM REGIONAL PHARMACY IN LENEXA, KANSAS)

Give information for the two (2) years following the completion of this proposal.

The fiscal year begins in January.

			CY 2017	CY 2018
		PATIENTS	45	65
A.	Utilization Data	VISITS	1,080	1,560
B.	Revenue from Services to Patients			
	1. Inpatient Services		$	$
	2. Outpatient Services		4,320,000	6,240,000
	3. Emergency Services			
	4. Other Operating Revenue (Specify)	See notes page		
		Gross Operating Revenue	$ 4,320,000	$ 6,240,000
C.	Deductions for Operating Revenue			
	1. Contractual Adjustments		$	$
	2. Provision for Charity Care		86,400	124,800
	3. Provisions for Bad Debt		43,200	62,400
		Total Deductions	$ 129,600	$ 187,200
NET OPERATING REVENUE			$ 4,190,400	$ 6,052,800
D.	Operating Expenses			
	1. Salaries and Wages		$ 333,500	$ 390,885
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,514,240	3,631,680
	4. Taxes		400,000	600,000
	5. Depreciation		3,333	7,500
	6. Rent		36,000	36,000
	7. Interest, other than Capital			
	8. Management Fees			
	a. Fees to Affiliates			
	b. Fees to Non-Affiliates			
	9. Other Expenses (Specify)	See notes page	33,600	48,000
		Total Operating Expenses	$ 3,320,673	$ 4,714,065
E.	Other Revenue (Expenses) -- Net (Specify)		$	$
NET OPERATING INCOME (LOSS)			$ 869,727	$ 1,338,735
F.	Capital Expenditures			
	1. Equipment		$ 200,000	$ 250,000
	2. Interest			
		Total Capital Expenditures	$ 200,000	$ 250,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$ 669,727	$ 1,088,735

SUPPLEMENTAL #1

CONSOLIDATED OPERATIONS: NURSING, HOME OFFICE, & PHARMACEUTICALS

June 23, 2016
12:14 pm

Give information for the two (2) years following the completion of this proposal.
The fiscal year begins in January.

			CY 2017	CY 2018
		PATIENTS	45	65
A.	Utilization Data	VISITS	1,080	1,560
B.	Revenue from Services to Patients			
	1. Inpatient Services		$	$
	2. Outpatient Services-home health nursing visits		4,579,200	6,614,400
	3. Emergency Services		0	0
	4. Other Operating Revenue (Specify)	See notes page	0	0
		Gross Operating Revenue	$ 4,579,200	$ 6,614,400
C.	Deductions for Operating Revenue			
	1. Contractual Adjustments		$ 0	$ 0
	2. Provision for Charity Care		91,584	132,288
	3. Provisions for Bad Debt		45,792	66,144
		Total Deductions	$ 137,376	$ 198,432
NET OPERATING REVENUE			$ 4,441,824	$ 6,415,968
D.	Operating Expenses			
	1. Salaries and Wages		$ 703,340	$ 874,490
	2. Physicians Salaries and Wages		0	0
	3. Supplies		2,526,811	3,649,838
	4. Taxes		400,000	600,000
	5. Depreciation		3,333	7,500
	6. Rent		47,628	48,209
	7. Interest, other than Capital		0	0
	8. Management Fees			
	a. Fees to Affiliates		0	0
	b. Fees to Non-Affiliates		0	0
	9. Other Expenses (Specify)	See notes page	41,398	58,783
		Total Operating Expenses	$ 3,722,511	$ 5,238,820
E.	Other Revenue (Expenses) -- Net (Specify)		$ 0	$ 0
NET OPERATING INCOME (LOSS)			$ 719,313	$ 1,177,148
F.	Capital Expenditures			
	1. Equipment		$ 200,000	$ 250,000
	2. Interest		0	0
		Total Capital Expenditures	$ 200,000	$ 250,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES			$ 519,313	$ 927,148

D9--OTHER EXPENSES

NURSING AND HOME OFFICE CHART

	2017	2018
Postage	300	300
RN mileage	5638	8143
office phone	900	900
i-pad use fee	960	1440
	7798	10783

PHARMACEUTICALS/SERVICES CHART

	2017	2018
Postage	300	300
office phone	900	900
Pharma/Shipping	32400	46800
	33600	48000

CONSOLIDATED OPERATIONS CHART

	2017	2018
Postage	600	600
RN mileage	5638	8143
office phone	1800	1800
iPad Use Fee	960	1440
Pharma/Shipping	32400	46800
	41398	58783

C(II).5. PLEASE IDENTIFY THE PROJECT'S AVERAGE GROSS CHARGE, AVERAGE DEDUCTION FROM OPERATING REVENUE, AND AVERAGE NET CHARGE.

Table Eleven-A: Average Charges, Deductions, Net Charges, Net Operating Income West Tennessee Nursing Operations Only		
	CY2017	**CY2018**
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	$5,760	$5,760
Average Expected Revenue Per Visit	$240	$240
Average Deduction from Operating Revenue per Patient	$173	$173
Average Deduction from Operating Revenue per Visit	$7	$7
Average Net Charge (Net Operating Revenue) Per Patient	$5,587	$5,587
Average Net Charge (Net Operating Revenue) Per Visit	$233	$233
Average Net Operating Income after Expenses, Per Patient	-$3,343	-$2,624
Average Net Operating Income after Expenses, Per Visit	-$139	-$109

Table Eleven-B: Average Charges, Deductions, Net Charges, Net Operating Income Combined W. TN Nursing and Out of State Pharmaceutical Operations		
	CY2017	**CY2018**
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue Per Patient	$101,760	$101,760
Average Expected Revenue Per Visit	$4,240	$4,240
Average Deduction from Operating Revenue per Patient	$3,053	$3,053
Average Deduction from Operating Revenue per Visit	$127	$127
Average Net Charge (Net Operating Revenue) Per Patient	$98,707	$98,707
Average Net Charge (Net Operating Revenue) Per Visit	$4,113	$4,113
Average Net Operating Income after Expenses, Per Patient	$15,985	$18,110
Average Net Operating Income after Expenses, Per Visit	$666	$755

C(II).6.A. PLEASE PROVIDE THE CURRENT AND PROPOSED CHARGE SCHEDULES FOR THE PROPOSAL. DISCUSS ANY ADJUSTMENT TO CURRENT CHARGES THAT WILL RESULT FROM THE IMPLEMENTATION OF THE PROPOSAL. ADDITIONALLY, DESCRIBE THE ANTICIPATED REVENUE FROM THE PROPOSED PROJECT AND THE IMPACT ON EXISTING PATIENT CHARGES.

There are no current charges because the home nursing service is proposed, not operational. There are no current charges to be impacted or adjusted as a result of this project.

AxelaCare negotiates a separate pricing structure with every insurer. Negotiated rates vary. They are proprietary and confidential. The insurers are billed only the negotiated amount. AxelaCare does not record or bill a "gross charge" that is discounted by "contractual adjustments" to yield "net revenue". The revenue figures shown in Section B of the Projected Data Charts are the billed or "expected" revenues, i.e., the projected receipts based on pre-negotiated reimbursement contracts, before deductions for charity and bad debt.

The table below (repeated from a prior section of the application) shows the average expected charge/revenue data per patient and per visit for AxelaCare's nursing services (home office and field staff) in West Tennessee. That is what AxelaCare is applying to add to its ongoing pharmaceutical distributions in Tennessee.

Table Three (Repeated): AxelaCare Healthcare Solutions, West Tennessee Nursing and Home Office (Excluding Pharmaceuticals)

	Year One--CY2017	Year Two-CY2018
Expected Nursing Revenue	$259,200	$374,400
Visits	1,080 visits	1,560 visits
Expected Average Revenue/Visit	$240	$240
Patients (Cases)	45	65
Expected Average Revenue/Patient	$5,760	$5,760

C(II).6.B. COMPARE THE PROPOSED CHARGES TO THOSE OF SIMILAR FACILITIES IN THE SERVICE AREA/ADJOINING SERVICE AREAS, OR TO PROPOSED CHARGES OF PROJECTS RECENTLY APPROVED BY THE HSDA. IF APPLICABLE, COMPARE THE PROJECTED CHARGES OF THE PROJECT TO THE CURRENT MEDICARE ALLOWABLE FEE SCHEDULE BY COMMON PROCEDURE TERMINOLOGY (CPT) CODE(S).

Although the applicant will not participate in Medicare for nursing services, Medicare pays for a 60-day episode of care at rates that vary by region and State. The approximate reimbursement of more than four visits is estimated by AxelaCare at $2400.

The only specialty infusion-specific charge data identified by the applicant in recently approved CON projects are in CN1406-018, approved for Coram/CVS Specialty Infusion Services two years ago, in June 2014. Coram projected average charges for its West Tennessee "specialty infusion patient" at $290-$348 (see page 87 of Coram CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections.

C(II).7. DISCUSS HOW PROJECTED UTILIZATION RATES WILL BE SUFFICIENT TO MAINTAIN COST-EFFECTIVENESS.

Cost-effectiveness is demonstrated by the positive operating margin of the Projected Data Chart for the consolidated Nursing and Pharmaceutical components of the home health project. The Pharmaceutical operations attributable to the project will absorb losses projected by the Nursing operations of the project.

C(II).8. DISCUSS HOW FINANCIAL VIABILITY WILL BE ENSURED WITHIN TWO YEARS; AND DEMONSTRATE THE AVAILABILITY OF SUFFICIENT CASH FLOW UNTIL FINANCIAL VIABILITY IS MAINTAINED.

The consolidated Nursing and Pharmaceutical Projected Data Chart demonstrates a positive cash flow beginning in Year One of the project.

C(II).9. DISCUSS THE PROJECT'S PARTICIPATION IN STATE AND FEDERAL REVENUE PROGRAMS, INCLUDING A DESCRIPTION OF THE EXTENT TO WHICH MEDICARE, TENNCARE/MEDICAID, AND MEDICALLY INDIGENT PATIENTS WILL BE SERVED BY THE PROJECT. IN ADDITION, REPORT THE ESTIMATED DOLLAR AMOUNT OF REVENUE AND PERCENTAGE OF TOTAL PROJECT REVENUE ANTICIPATED FROM EACH OF TENNCARE, MEDICARE, OR OTHER STATE AND FEDERAL SOURCES FOR THE PROPOSAL'S FIRST YEAR OF OPERATION.

The anticipated payor mix for home care nursing services is 98% commercial (including Blue Cross and Medicare replacement plans), and 2% charity.

Year One expected revenue will be $259,200. Commercial payor mix at 98% will be $254,016. Charity care at 2% will be $5,184.

C(II).10. PROVIDE COPIES OF THE BALANCE SHEET AND INCOME STATEMENT FROM THE MOST RECENT REPORTING PERIOD OF THE INSTITUTION, AND THE MOST RECENT AUDITED FINANCIAL STATEMENTS WITH ACCOMPANYING NOTES, IF APPLICABLE. FOR NEW PROJECTS, PROVIDE FINANCIAL INFORMATION FOR THE CORPORATION, PARTNERSHIP, OR PRINCIPAL PARTIES INVOLVED WITH THE PROJECT. COPIES MUST BE INSERTED AT THE END OF THE APPLICATION, IN THE CORRECT ALPHANUMERIC ORDER AND LABELED AS ATTACHMENT C, ECONOMIC FEASIBILITY--10.

These are provided for AxelaCare's parent company, in Attachment C, Economic Feasibility--10.

C(II)11. DESCRIBE ALL ALTERNATIVES TO THIS PROJECT WHICH WERE CONSIDERED AND DISCUSS THE ADVANTAGES AND DISADVANTAGES OF EACH ALTERNATIVE, INCLUDING BUT NOT LIMITED TO:

A. A DISCUSSSION REGARDING THE AVAILABILITY OF LESS COSTLY, MORE EFFECTIVE, AND/OR MORE EFFICIENT ALTERNATIVE METHODS OF PROVIDING THE BENEFITS INTENDED BY THE PROPOSAL. IF DEVELOPMENT OF SUCH ALTERNATIVES IS NOT PRACTICABLE, THE APPLICANT SHOULD JUSTIFY WHY NOT, INCLUDING REASONS AS TO WHY THEY WERE REJECTED.

B. THE APPLICANT SHOULD DOCUMENT THAT CONSIDERATION HAS BEEN GIVEN TO ALTERNATIVES TO NEW CONSTRUCTION, E.G., MODERNIZATION OR SHARING ARRANGEMENTS. IT SHOULD BE DOCUMENTED THAT SUPERIOR ALTERNATIVES HAVE BEEN IMPLEMENTED TO THE MAXIMUM EXTENT PRACTICABLE.

Continuation of the status quo was rejected for reasons discussed at length throughout the application. Current patient care problems that need to be resolved include:

- Difficulties in finding agencies that are immediately staffed and ready to start patient infusions at home and are willing to provide care for sessions longer than 2 hours;

- Less than desirable results in training other agency's staff in the consistent and effective use of AxelaCare's handheld CareExchange technology, which is an optimal tool for ensuring complete, accurate, usable and real-time availability of patient clinical data to the team pharmacist and referring physician.

C(III).1. LIST ALL EXISTING HEALTH CARE PROVIDERS (I.E., HOSPITALS, NURSING HOMES, HOME CARE ORGANIZATIONS, ETC.) MANAGED CARE ORGANIZATIONS, ALLIANCES, AND/OR NETWORKS WITH WHICH THE APPLICANT CURRENTLY HAS OR PLANS TO HAVE CONTRACTUAL AND/OR WORKING RELATIONSHIPS, E.G., TRANSFER AGREEMENTS, CONTRACTUAL AGREEMENTS FOR HEALTH SERVICES.

AxelaCare has, and expects to develop, referral and working relationships with a large number of hospitals, specialty medical practices and home health agencies in the Memphis area and the Jackson area.

C(III).2. DESCRIBE THE POSITIVE AND/OR NEGATIVE EFFECTS OF THE PROPOSAL ON THE HEALTH CARE SYSTEM. PLEASE BE SURE TO DISCUSS ANY INSTANCES OF DUPLICATION OR COMPETITION ARISING FROM YOUR PROPOSAL, INCLUDING A DESCRIPTION OF THE EFFECT THE PROPOSAL WILL HAVE ON THE UTILIZATION RATES OF EXISTING PROVIDERS IN THE SERVICE AREA OF THE PROJECT.

The applicant believes that the benefits of this project far outweigh the minuscule utilization impact that 65 AxelaCare home nursing patients would have on the overall array of 52 agencies serving West Tennessee. First, the AxelaCare patient volume is less than two-tenths of one percent of the 39,026 patients served by the agencies in this area last year. Second, at its current two-year rate of increase the agencies' caseloads in this area will increase by 3,092 patients by Year Two of the AxelaCare project. That should offset any conceivable adverse impact on existing agencies as a group.

On the positive side, the project has clear patient benefits for the health system. The project will encourage movement of IVIG infusion patients out of costlier and less convenient settings, where they now have to go in order to get a timely start of dosing for their disorders. It will manage their conditions with specialty-trained infusion nurses, using state-of-the-art information technology that enhances real-time communication between the care team and the patient's physician. The unique CareExchange technology also helps compile ever-larger databases that are usable for ongoing research to improve the effectiveness of these complex and evolving medications and their administration.

C(III).3. PROVIDE THE CURRENT AND/OR ANTICIPATED STAFFING PATTERN FOR ALL EMPLOYEES PROVIDING PATIENT CARE FOR THE PROJECT. THIS CAN BE REPORTED USING FTE'S FOR THESE POSITIONS. IN ADDITION, PLEASE COMPARE THE CLINICAL STAFF SALARIES IN THE PROPOSAL TO PREVAILING WAGE PATTERNS IN THE SERVICE AREA AS PUBLISHED BY THE TENNESSEE DEPARTMENT OF LABOR & WORKFORCE DEVELOPMENT AND/OR OTHER DOCUMENTED SOURCES.

RN's, and in particular infusion RN's, are the project's only clinical staff. Table Twelve below shows the Department of Labor and Workforce Development's 2015 occupational wage salary survey information for registered nurses.

Table Twelve: TDOL Surveyed Average Salaries for the Region				
Position	Entry Level	Mean	Median	Experienced
RN	$45,906	$59,308	$58,872	$66,019

Source: TDLWD Occupational Wages Surveys, 2015.

Please see the following page for Table Thirteen, which projects the project's required FTE's and salary ranges. The project will require the employment and deployment of only 6 FTE's in the nursing component of care (The pharmaceutical component based in Lexena, Kansas will not require additional staff to supply medications to the proposed nursing agency).

Table Thirteen-A: Axelacare Healthcare Solutions-- West Tennessee
Projected Staffing

Position Type (RN, etc.)	Yr 1-2017 FTE's	Yr 2-2018 FTE's	Each Position		Total CY2017 Salaries		Total CY2018 Salaries	
			Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Office Positions, Management and Clerical								
RN Home Care Director Memphis / Half Time in Office	0.50	0.50	$85,000	$103,000	$42,500	$51,500	$43,775	$53,045
Account Executive	1.00	1.00	$65,000	$85,000	$65,000	$85,000	$66,950	$87,550
Administrative Assistant (corporate-remote)	0.50	1.00	$35,360	$41,600	$17,680	$20,800	$36,421	$42,848
Subtotal, Home Office FTE's	*2.00*	*2.50*	*$185,360*	*$229,600*	*$125,180*	*$157,300*	*$147,145*	*$183,443*
Field Positions (Direct Patient Care)								
RN Home Care Director, Memphis / Half-Time Home in Field	0.50	0.50	$85,000	$103,000	$42,500	$51,500	$42,500	$51,500
Infusion RN's in the Field	2.00	3.00	$76,960	$87,360	$153,920	$174,720	$230,880	$262,080
Subtotal, Nurse FTE's Providing Home Infusion	*2.50*	*3.50*	*$161,960*	*$190,360*	*$196,420*	*$226,220*	*$273,380*	*$313,580*
Total FTE's	***4.50***	***6.00***	***$347,320***	***$419,960***	***$321,600***	***$383,520***	***$420,526***	***$497,023***
Salaries Plus Benefits (@15%)					***$369,840***	***$441,048***	***$483,605***	***$571,576***

Source: Axelacare management.
Note: RN Home Care Director spends half time as infusion nurse in the field. Table reflects that division of FTE's and salaries.

Table Thirteen-B: Axelacare Healthcare Solutions-- West Tennessee
Projected Staffing - drug delivery

Position Type (RN, etc.)	Yr 1-2017 FTE's	Yr 2-2018 FTE's	Each Position		Total CY2017 Salaries		Total CY2018 Salaries	
			Minimum	Maximum	Minimum	Maximum	Minimum	Maximum
Office Positions, Management and Clerical								
Pharmacist	1.00	1.00	$145,000	$180,000	$145,000	$180,000	$149,350	$185,400
Techs	1.00	1.00	$40,000	$50,000	$40,000	$50,000	$41,200	$51,500
Delivery	1.00	1.00	$25,000	$35,000	$25,000	$35,000	$25,750	$36,050
BackOffice	2.00	3.00	$40,000	$60,000	$80,000	$120,000	$123,600	$185,400
					$0	$0	$0	$0
Subtotal, Home Office FTE's	*5.00*	*6.00*	*$250,000*	*$325,000*	*$290,000*	*$385,000*	*$339,900*	*$458,350*
Salaries Plus Benefits (@15%)					***$333,500***	***$442,750***	***$390,885***	***$527,103***

Source: Axelacare management.
Note: RN Home Care Director spends half time as infusion nurse in the field. Table reflects that division of FTE's and salaries.

C(III).4. DISCUSS THE AVAILABILITY OF AND ACCESSIBILITY TO HUMAN RESOURCES REQUIRED BY THE PROPOSAL, INCLUDING ADEQUATE PROFESSIONAL STAFF, AS PER THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, AND/OR THE DIVISION OF MENTAL RETARDATION SERVICES LICENSING REQUIREMENTS.

AxelaCare Health Solutions, LLC is familiar with State requirements for staffing a licensed home health agency. The small number of skilled RN's (4 FTE's) that are needed to operate the project are readily available through AxelaCare's corporate recruiting resources.

C(III).5. VERIFY THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSING CERTIFICATION AS REQUIRED BY THE STATE OF TENNESSEE FOR MEDICAL/CLINICAL STAFF. THESE INCLUDE, WITHOUT LIMITATION, REGULATIONS CONCERNING PHYSICIAN SUPERVISION, CREDENTIALING, ADMISSIONS PRIVILEGES, QUALITY ASSURANCE POLICIES AND PROGRAMS, UTILIZATION REVIEW PPOLICIES AND PROGRAMS, RECORD KEEPING, AND STAFF EDUCATION.

The applicant so verifies.

C(III).6. DISCUSS YOUR HEALTH CARE INSTITUTION'S PARTICIPATION IN THE TRAINING OF STUDENTS IN THE AREAS OF MEDICINE, NURSING, SOCIAL WORK, ETC. (I.E., INTERNSHIPS, RESIDENCIES, ETC.).

The applicant has no plans at this time to participate in training programs.

C(III).7(a). PLEASE VERIFY, AS APPLICABLE, THAT THE APPLICANT HAS REVIEWED AND UNDERSTANDS THE LICENSURE REQUIREMENTS OF THE DEPARTMENT OF HEALTH, THE DEPARTMENT OF MENTAL HEALTH AND DEVELOPMENTAL DISABILITIES, THE DIVISION OF MENTAL RETARDATION SERVICES, AND/OR ANY APPLICABLE MEDICARE REQUIREMENTS.

The applicant so verifies.

C(III).7(b). PROVIDE THE NAME OF THE ENTITY FROM WHICH THE APPLICANT HAS RECEIVED OR WILL RECEIVE LICENSURE, CERTIFICATION, AND/OR ACCREDITATION

LICENSURE: The applicant will seek a limited home health agency license from the Board for Licensure of Healthcare Facilities, Tennessee Department of Health (TDH). The applicant's Specialty Pharmacy already holds a Tennesse non-resident pharmacy license and its associated Sterile Compounding License (granted by TDH).

CERTIFICATION: The applicant will not seek Medicare or TennCare certification.

ACCREDITATION: AxelaCare is Joint Commission accredited nationally and holds the Joint Commission's Gold Seal of Approval. AxelaCare's Specialty Pharmacy Program is also accredited by URAC (originally named the "Utilization Review Accreditation Program").

C(III).7(c). IF AN EXISTING INSTITUTION, PLEASE DESCRIBE THE CURRENT STANDING WITH ANY LICENSING, CERTIFYING, OR ACCREDITING AGENCY OR AGENCY.

AxelaCare's Lexena, Kansas Specialty Pharmacy and Sterile Compounding Licenses are in good standing.

C(III).7(d). FOR EXISTING LICENSED PROVIDERS, DOCUMENT THAT ALL DEFICIENCIES (IF ANY) CITED IN THE LAST LICENSURE CERTIFICATION AND INSPECTION HAVE BEEN ADDRESSED THROUGH AN APPROVED PLAN OF CORRECTION. PLEASE INCLUDE A COPY OF THE MOST RECENT LICENSURE/CERTIFICATION INSPECTION WITH AN APPROVED PLAN OF CORRECTION.

Please see the Attachments for copies of the applicant's licenses and most recent surveys and approved plans of correction.

C(III)8. DOCUMENT AND EXPLAIN ANY FINAL ORDERS OR JUDGMENTS ENTERED IN ANY STATE OR COUNTRY BY A LICENSING AGENCY OR COURT AGAINST PROFESSIONAL LICENSES HELD BY THE APPLICANT OR ANY ENTITIES OR PERSONS WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE APPLICANT. SUCH INFORMATION IS TO BE PROVIDED FOR LICENSES REGARDLESS OF WHETHER SUCH LICENSE IS CURRENTLY HELD.

None have been identified.

C(III)9. IDENTIFY AND EXPLAIN ANY FINAL CIVIL OR CRIMINAL JUDGMENTS FOR FRAUD OR THEFT AGAINST ANY PERSON OR ENTITY WITH MORE THAN A 5% OWNERSHIP INTEREST IN THE PROJECT.

None have been identified.

C(III)10. IF THE PROPOSAL IS APPROVED, PLEASE DISCUSS WHETHER THE APPLICANT WILL PROVIDE THE THSDA AND/OR THE REVIEWING AGENCY INFORMATION CONCERNING THE NUMBER OF PATIENTS TREATED, THE NUMBER AND TYPE OF PROCEDURES PERFORMED, AND OTHER DATA AS REQUIRED.

Yes. The applicant will provide the requested data consistent with Federal HIPAA requirements.

PROOF OF PUBLICATION

To be provided under separate cover during the Supplemental Responses cycle.

DEVELOPMENT SCHEDULE

1. PLEASE COMPLETE THE PROJECT COMPLETION FORECAST CHART ON THE NEXT PAGE. IF THE PROJECT WILL BE COMPLETED IN MULTIPLE PHASES, PLEASE IDENTIFY THE ANTICIPATED COMPLETION DATE FOR EACH PHASE.

The Project Completion Forecast Chart is provided after this page.

2. IF THE RESPONSE TO THE PRECEDING QUESTION INDICATES THAT THE APPLICANT DOES NOT ANTICIPATE COMPLETING THE PROJECT WITHIN THE PERIOD OF VALIDITY AS DEFINED IN THE PRECEDING PARAGRAPH, PLEASE STATE BELOW ANY REQUEST FOR AN EXTENDED SCHEDULE AND DOCUMENT THE "GOOD CAUSE" FOR SUCH AN EXTENSION.

Not applicable. The applicant anticipates completing the project within the period of validity.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision Date, as published in Rule 68-11-1609(c):

September 28, 2016

Assuming the CON decision becomes the final Agency action on that date, indicate the number of days from the above agency decision date to each phase of the completion forecast.

PHASE	DAYS REQUIRED	Anticipated Date (MONTH /YEAR)
1. Architectural & engineering contract signed		
2. Construction documents approved by TDH		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete		
10. * Issuance of license	93	12-30-16
11. *Initiation of service	111	1-1-17
12. Final architectural certification of payment		
13. Final Project Report Form (HF0055)		

*** For projects that do NOT involve construction or renovation: please complete items 10-11 only.**

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

INDEX OF ATTACHMENTS

A.4 Ownership--Legal Entity and Organization Chart (if applicable)

A.6 Site Control

B.III. Plot Plan

B.IV. Floor Plan

C, Need--1 Documentation of Project-Specific Review Criteria

1. Performance Improvement Plan
2. Patient Satisfaction Survey
3. Emergency Response Protocols
4. Financial Assistance Program

C, Need--1.A.3. Qualifications of Professional Staff

C, Need--3 Service Area Maps

C, Economic Feasibility--2 Documentation of Availability of Funding

C, Economic Feasibility--10 Financial Statements of Funding Source

Miscellaneous Information

1. Patient Origin Projection for the Project
2. TDH Report of HHA's Currently Serving Area Residents
3. URAC--Specialty Pharmacy
4. TennCare Enrollment in Service Area
5. Appraisal of Project Site

Support Letters

B.III.--Plot Plan

CHEYENNE JOHNSON

Assessor of Property

Shelby County, TN

Property Search | Property Details | Maps

Property

Property Address
5100 POPLAR AVE

Parcel ID
056033 00237

Owner Name
CLARK TOWER LLC

2015 Appraised Value
$22,010,300

Property/Assessment Details
Click Here

Deed Information
Click Here

County Tax
Click Here

City Tax
Click Here

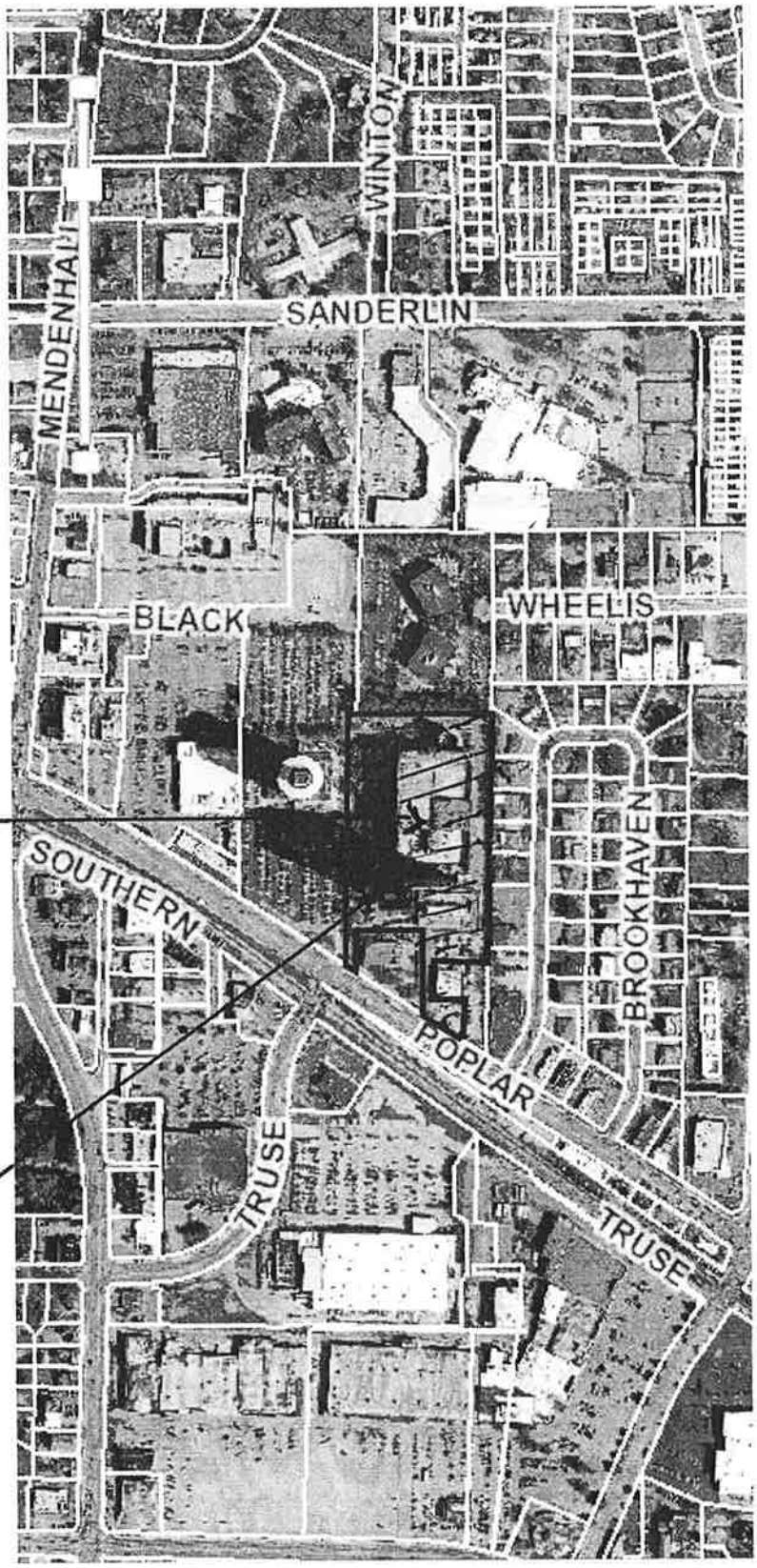
PROJECT ON
27th FLOOR

CLARK TOWER

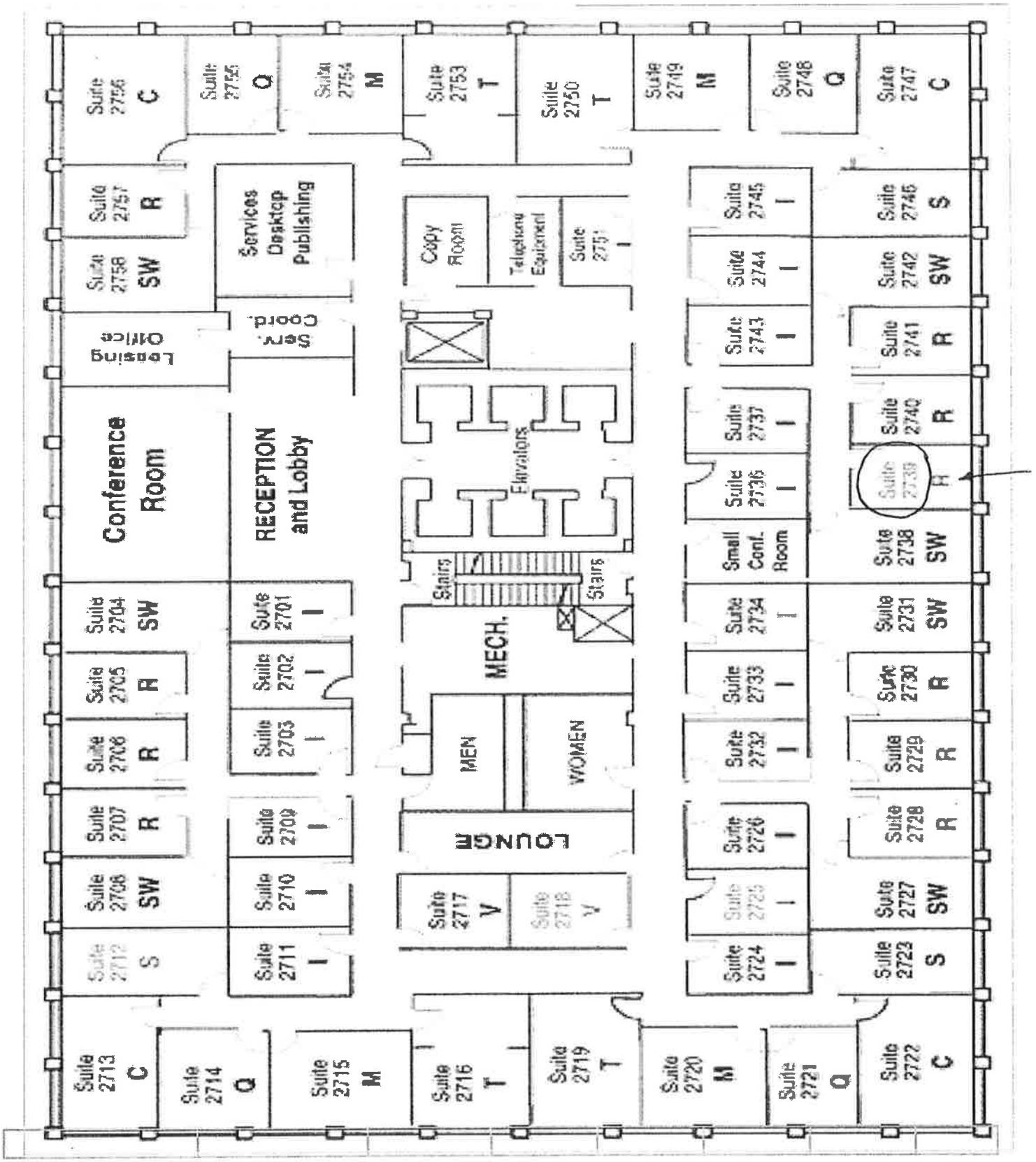
SITE 7.79 acres

Layers

Search Property Sales



B.IV.--Floor Plan


Suite 2756 C
Suite 2755 Q
Suite 2754 M
Suite 2753 T
Suite 2750 T
Suite 2749 M
Suite 2748 Q
Suite 2747 C
Suite 2757 R
Suite 2758 SW
Services Desktop Publishing
Copy Room
Telephone Equipment
Suite 2751 I
Suite 2745 I
Suite 2746 S
Suite 2744 I
Suite 2742 SW
Leasing Office
Concierge
Suite 2743 I
Suite 2741 R
Conference Room
RECEPTION and Lobby
Elevators
Suite 2737 I
Suite 2740 R
Suite 2736 I
Suite 2739 R
Small Conf. Room
Suite 2738 SW
Suite 2704 SW
Suite 2701 I
Stairs
Stairs
Suite 2734 I
Suite 2731 SW
Suite 2705 R
Suite 2702 I
MECH.
Suite 2733 I
Suite 2730 R
Suite 2706 R
Suite 2703 I
MEN
WOMEN
Suite 2732 I
Suite 2729 R
Suite 2707 R
Suite 2709 I
LOUNGE
Suite 2726 I
Suite 2728 R
Suite 2708 SW
Suite 2710 I
Suite 2717 V
Suite 2718 V
Suite 2725 I
Suite 2727 SW
Suite 2712 S
Suite 2711 I
Suite 2724 I
Suite 2723 S
Suite 2713 C
Suite 2714 Q
Suite 2715 M
Suite 2716 T
Suite 2719 T
Suite 2720 M
Suite 2721 Q
Suite 2722 C

C, Need--3
Service Area Maps

AXELACARE WEST TENNESSEE
PROJECT SERVICE AREA

C, Economic Feasibility--2
Documentation of Availability of Funding

AXELA Care

Experience. The Difference.

15529 College Blvd
Lenexa, KS 66219

Toll-free: 877.342.9352
Fax: 877.542.9352

www.AxelaCare.com

June 10, 2016

Melanie Hill, Executive Director
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application to Establish a Home Health Agency
Shelby County, Tennessee

Dear Mrs. Hill:

AxelaCare Health Solutions, LLC is filing a Certificate of Need application to establish a home health agency in Shelby County, limited to providing home infusion of immune globulin pharmaceuticals.

AxelaCare Health Solutions, LLC is wholly owned through several wholly owned subsidiaries by UnitedHealth Group, Inc., a publicly traded company.

I am writing to confirm that the project's capital cost, estimated at only approximately $58,000, will be funded by a cash transfer to the applicant through its parent company. As Controller of Axelacare Holdings, Inc., parent company of AxelaCare Health Solutions, LLC, I am authorized to make that commitment. The availability of sufficient cash for the project is shown in financial statements in the Attachments to the application.

Clay Collins
Controller
Axelacare Holdings, Inc.

C, Economic Feasibility--10
Financial Statements

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2015

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP®

UnitedHealth Group Incorporated
(Exact name of registrant as specified in its charter)

Delaware	**41-1321939**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
UnitedHealth Group Center **9900 Bren Road East** **Minnetonka, Minnesota**	**55343**
(Address of principal executive offices)	**(Zip Code)**

(952) 936-1300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, $.01 PAR VALUE	**NEW YORK STOCK EXCHANGE, INC.**
(Title of each class)	**(Name of each exchange on which registered)**

Securities registered pursuant to Section 12(g) of the Act: NONE

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one)

Large accelerated filer ☒ Accelerated filer ☐
Non-accelerated filer ☐ Smaller reporting company ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2015 was $114,440,856,791 (based on the last reported sale price of $122.00 per share on June 30, 2015, on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.

As of January 29, 2016, there were 950,673,998 shares of the registrant's Common Stock, $.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2016 Annual Meeting of Shareholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

UnitedHealth Group
Consolidated Balance Sheets

(in millions, except per share data)	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 10,923	$ 7,495
Short-term investments	1,988	1,741
Accounts receivable, net of allowances of $333 and $260	6,523	4,252
Other current receivables, net of allowances of $138 and $156	6,801	5,498
Assets under management	2,998	2,962
Deferred income taxes	860	556
Prepaid expenses and other current assets	1,546	1,052
Total current assets	31,639	23,556
Long-term investments	18,792	18,827
Property, equipment and capitalized software, net of accumulated depreciation and amortization of $3,173 and $2,954	4,861	4,418
Goodwill	44,453	32,940
Other intangible assets, net of accumulated amortization of $3,128 and $2,685	8,391	3,669
Other assets	3,247	2,972
Total assets	$ 111,383	$ 86,382
Liabilities, redeemable noncontrolling interests and equity		
Current liabilities:		
Medical costs payable	$ 14,330	$ 12,040
Accounts payable and accrued liabilities	11,994	9,247
Other policy liabilities	7,798	5,965
Commercial paper and current maturities of long-term debt	6,634	1,399
Unearned revenues	2,142	1,972
Total current liabilities	42,898	30,623
Long-term debt, less current maturities	25,460	16,007
Future policy benefits	2,496	2,488
Deferred income taxes	3,587	2,065
Other liabilities	1,481	1,357
Total liabilities	75,922	52,540
Commitments and contingencies (Note 13)		
Redeemable noncontrolling interests	1,736	1,388
Equity:		
Preferred stock, $0.001 par value — 10 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.01 par value — 3,000 shares authorized; 953 and 954 issued and outstanding	10	10
Additional paid-in capital	29	—
Retained earnings	37,125	33,836
Accumulated other comprehensive loss	(3,334)	(1,392)
Nonredeemable noncontrolling interest	(105)	—
Total equity	33,725	32,454
Total liabilities, redeemable noncontrolling interests and equity	$ 111,383	$ 86,382

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Operations

(in millions, except per share data)	For the Years Ended December 31, 2015	2014	2013
Revenues:			
Premiums	$127,163	$115,302	$109,557
Products	17,312	4,242	3,190
Services	11,922	10,151	8,997
Investment and other income	710	779	745
Total revenues	157,107	130,474	122,489
Operating costs:			
Medical costs	103,875	93,633	89,659
Operating costs	24,312	21,263	18,941
Cost of products sold	16,206	3,826	2,891
Depreciation and amortization	1,693	1,478	1,375
Total operating costs	146,086	120,200	112,866
Earnings from operations	11,021	10,274	9,623
Interest expense	(790)	(618)	(708)
Earnings before income taxes	10,231	9,656	8,915
Provision for income taxes	(4,363)	(4,037)	(3,242)
Net earnings	5,868	5,619	5,673
Earnings attributable to noncontrolling interests	(55)	—	(48)
Net earnings attributable to UnitedHealth Group common stockholders	$ 5,813	$ 5,619	$ 5,625
Earnings per share attributable to UnitedHealth Group common stockholders:			
Basic	$ 6.10	$ 5.78	$ 5.59
Diluted	$ 6.01	$ 5.70	$ 5.50
Basic weighted-average number of common shares outstanding	953	972	1,006
Dilutive effect of common share equivalents	14	14	17
Diluted weighted-average number of common shares outstanding	967	986	1,023
Anti-dilutive shares excluded from the calculation of dilutive effect of common share equivalents	8	6	8
Cash dividends declared per common share	$ 1.8750	$ 1.4050	$ 1.0525

See Notes to the Consolidated Financial Statements

UnitedHealth Group
Consolidated Statements of Comprehensive Income

(in millions)	For the Years Ended December 31, 2015	2014	2013
Net earnings	$ 5,868	$ 5,619	$ 5,673
Other comprehensive loss:			
Gross unrealized (losses) gains on investment securities during the period	(123)	476	(543)
Income tax effect	44	(173)	196
Total unrealized (losses) gains, net of tax	(79)	303	(347)
Gross reclassification adjustment for net realized gains included in net earnings	(141)	(211)	(181)
Income tax effect	53	77	66
Total reclassification adjustment, net of tax	(88)	(134)	(115)
Total foreign currency translation losses	(1,775)	(653)	(884)
Other comprehensive loss	(1,942)	(484)	(1,346)
Comprehensive income	3,926	5,135	4,327
Comprehensive income attributable to noncontrolling interests	(55)	—	(48)
Comprehensive income attributable to UnitedHealth Group common stockholders	$ 3,871	$ 5,135	$ 4,279

See Notes to the Consolidated Financial Statements

Miscellaneous Information

AxelaCare Health Solutions--Shelby County Patient Origin Projection CY2017-CY2018				
County	Percent of Total Patients	Cumulative Percent of Total Patients	Year One CY2017 Patients	Year Two CY2018 Patients
Shelby	59.2%	59.2%	27	38
Madison	6.4%	65.6%	3	4
Tipton	4.1%	69.7%	2	3
Gibson	3.2%	72.9%	1	2
Fayette	2.8%	75.7%	1	2
Dyer	2.4%	78.1%	1	2
Weakley	2.2%	80.3%	1	1
Henry	2.1%	82.4%	1	1
Obion	2.0%	84.4%	1	1
Henderson	1.8%	86.2%	1	1
Lauderdale	1.8%	88.0%	1	1
Carroll	1.7%	89.7%	1	1
Hardeman	1.7%	91.4%	1	1
McNairy	1.7%	93.1%	1	1
Hardin	1.6%	94.7%	1	1
Chester	1.1%	95.8%	0	1
Haywood	1.1%	96.9%	0	1
Benton	1.0%	97.9%	0	1
Crockett	0.9%	98.8%	0	1
Decatur	0.7%	99.5%	0	0
Lake	0.5%	100.0%	0	0
Service Area Total	*100.0%*		*45*	*65*

Source: Patient projections in proportion to county populations, 2016.

CHEYENNE JOHNSON

Assessor of Property

Property Location and Owner Information		2015 Appraisal and Assessment Information	
Parcel ID:	056033 00237	Class:	COMMERCIAL
		Land Appraisal:	$ 5,155,600
Property Address:	5100 POPLAR AVE	Building Appraisal:	$ 16,854,700
Municipal Jurisdiction:	MEMPHIS	Total Appraisal:	$ 22,010,300
Neighborhood Number:	00712E56		
Tax Map Page:	154E	Total Assessment:	$ 8,804,120
Land Square Footage:			
Acres:	7.7900	Greenbelt Land:	$ 0
Lot Dimensions:	139.71 X 237.97 IRR	Homesite Land:	$ 0
Subdivision Name:	CLARK TOWER SD RESUB OF LOT 2	Homesite Building:	$ 0
Subdivision Lot Number:	2A	Greenbelt Appraisal:	$ 0
Plat Book and Page:	216-030	Greenbelt Assessment:	$ 0
Number of Improvements:	1		
Owner Name:	CLARK TOWER LLC	**Click Here for 2014 Values**	
In Care Of:		**View: Assessor's GIS Map**	
Owner Address:	2328 10TH AVE N STE 401	**View: GIS Parcel Map**	
Owner City/State/Zip:	LAKE WORTH, FL 33461 6606		

Commercial Structure Information	
Land Use:	- OFFICE HIGH
Total Living Units:	
Structure Type:	OFFICE BLDG H-R 5ST
Year Built:	1973
Investment Grade:	B
Building Square Footage:	1172656

Other Buildings on Site for this Property
See Permits Filed for this Property
See Sales Data for this Property

SUPPORT LETTERS

Wesley Neurology Clinic

Center for the Diagnosis, Treatment and Research of Neurological Disorders

Bola Adumolekun, M.D.
Tulio E. Bertorini, M.D.
Yaohui Chai, M.D.
Gregory J. Condon, M.D.
Hafiz A. Elahi, M.D.
Nada El Audary, M.D.
Mark LeDoux, M.D.
Jesus F. Martinez, M.D.
Rekha Pillai, M.D.

Nancy F. Baker
Administrator

Central Office
1211 Union Ave
Suite 400
Memphis, TN 38104
(901) 725-8920

East Office
8000 Centerview Pkwy
Suite 305
Memphis, TN 38018
(901) 624-2960

MRI Center
8000 Centerview Pkwy
Suite 101
Memphis, TN 38018
(901) 624-0384

North Office
3950 New Covington Pike
Suite 270
Memphis, TN 38128
(901) 387-2120

wesleyneurology.com

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Wesley Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system--some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

Having companies like AxelaCare that specialize in pharmacy and IgG infusion nursing in the home setting provides a great alternative to treat these patients. Identifying companies that can provide home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed,. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

I support Axelacare's application for a Certificate of Need to provide these specialized services. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Tulio Bertorini M.D.

June 9, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

I am a Registered Nurse working for Memphis Neurology. We are a multi-physician specialty medical practice in Memphis treating patients with disorders related to the nervous system. We see patients from Memphis and several counties surrounding Shelby County.

In the past, we have attempted to identify home health agencies that will treat our patients requiring immune globulin (IvIg) therapy in the home. This is an infused therapy given by IV which requires specially trained skilled nurses to administer. The RN goes to the home, starts an IV, administers the drug and monitors the patient throughout the infusion. Due to the nature of the drug and the dose given, this can often require the infusion to last 4-8 hours and must be given over consecutive days. Consequently, many home health agencies decline these patients because they do not have the trained staff or the number of nurses available to service.

Recently, I have had patients that should have received this therapy in the home but I could not identify an agency in West Tennessee that could service this type of patient.

I am requesting that you approve Axelacare's request for CON to provide services for our patients. There is an unmet need in our area and having Axelacare as an option to provide these services could improve the quality and timeliness of care our patients receive.

Sincerely,

Rivers Collison, RN, BSN

Rivers Collison, RN

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Memphis Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system--some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed,. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Shankar Natarajan, M.D.

Rahul Sonone, M.D.

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Memphis Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system,some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

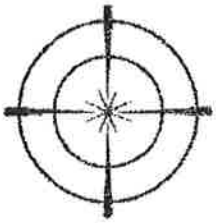
We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed,. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Shankar Natarajan, M.D.

Rahul Sonone, M.D.



INTERNATIONAL
PRECISION MEDICINE
ASSOCIATES

2200 Pennsylvania Avenue NW
4th Floor East Tower
Washington, DC 20037
888-727-6910
Fax 202-765-2456

May 17, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at International Precision Medicine Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in West Tennessee.

International Precision Medicine Associates is a specialty medical practice of two physicians, one naturopathic physician, and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in West Tennessee. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time--and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

Respectfully submitted,

Charles Gant, M.D., Ph.D.

National Integrated Health Associates
Leaders in Integrative Medicine and Biological Dentistry

5/16/16

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at National Integrated Health Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in Arlington, TN.

National Integrated Health Associates is a specialty medical practice of six physicians and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in Shelby County. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time–and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

Respectfully submitted,

Tracy Freeman, M.D.

Susan Greenberg FNP

Susan Greenberg FNP-BC

5225 Wisconsin Avenue, Suite 402 • Washington, D.C. 20015
(202) 237-7000 www.NIHAdc.com Fax (202) 237-001

EMAILED SUPPORT STATEMENT

NOTE: Mr. Hartman, a Pharmacist, resides in Hamilton County.

From: Steven Hartman <chadrx2005@gmail.com>
Date: June 10, 2016 at 8:46:23 AM CDT
To: Derrek Blake <dblake@axelacare.com>
Subject: Re: AxelaCare Health Solutions TN Letter (Derrek Blake)

To Whom It May Concern:

I would like to express my professional and personal opinions regarding the arrangement of nursing home care for HyQvia infusion treatment. As a pharmacist I have seen the benefits of streamlining any treatment for patients. The least complex process is always the most advantageous for the patient and usually leads to a higher patient compliance rate. I believe reducing the number of patient contacts by the ability to schedule nursing care through a single contact at AxelaCare will help patients. From a personal/patient point of view I found myself engaging in some phone tag when scheduling my initial nursing care visit. This seems to have pushed back my start date a few days. Not a problem for me personally, but could be a potential issue for some patients in the future. Thank you for your time and attention to my viewpoints. I hope this helps in the decision making process and advances patient care to the very best it can be.

Sincerely,
Chad Hartman, PharmD

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

JOHN WELLBORN, being first duly sworn, says that he is the lawful agent of the applicant named in this application, that this project will be completed in accordance with the application to the best of the agent's knowledge, that the agent has read the directions to this application, the Rules of the Health Services and Development Agency, and T.C.A. § 68-11-1601, *et seq.*, and that the responses to this application or any other questions deemed appropriate by the Health Services and Development Agency are true and complete to the best of the agent's knowledge.

John T. Wellborn
SIGNATURE/TITLE

Sworn to and subscribed before me this 13th day of June (Month), 2016 (Year) a Notary Public in and for the County/State of DAVIDSON

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

NOTARY PUBLIC

My commission expires July 2, (Month/Day) 2018 (Year).

Supplemental #1
-COPY-

AxelaCare Health Solutions, LLC

CN1606-022

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

June 22, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

1. Section A. Applicant Profile, Item 1

a. The Letter of Intent notes the applicant's proposed site is located on the 27th floor at 5100 Poplar Avenue, Memphis, TN. Please revise.

Attached after this page is revised page 1R, adding "Suite 2739" to the address for the site, so it exactly agrees with the Letter of Intent.

b. The applicant notes the proposed site is located in Johnson (Kansas) County. Please revise to reflect Shelby County, TN.

Revised page 1R following this page corrects that county name.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

2. Section A, Applicant Profile, Item 12 and 13

a. If the applicant does not plan to provide home health infusion nursing services to TennCare/Medicare enrollees, where would enrollees be referred for those services? If a home health provider is not located, would an enrollee be required to travel on-site for infusion services? Please be specific.

Medicare patients must meet strict Federal guidelines -- "Conditions of Participation" -- to qualify for home infusion nursing. The most difficult of these to meet is being "homebound". The few patients who meet that and the other criteria can only receive home nursing from a Medicare-certified home health agency. AxelaCare is not such an agency and cannot serve Medicare or TennCare referrals. The applicant's survey of existing agencies (Table One in the application) identified only three area agencies that are currently able and prepared to infuse patients with IVIG at home--and two of them are limited to six (6) counties out of the twenty-one (21)-county service area.

Because very few TennCare/Medicare patients qualify under reimbursement rules for home infusion of IVIG products, and because many agencies do not do home infusion of IVIG products, the applicant believes that most TennCare/Medicare patients needing IVIG therapy are being referred by their physicians to hospital outpatient infusion centers, to freestanding infusion centers, or to physician practices that provide such infusions.

b. Please clarify if the applicant's licensed home infusion pharmacy serves non-TennCare/Medicare patients in the proposed 21 County service area.

Yes; the AxelaCare regional pharmacy in Kansas has a Tennessee non-resident pharmacy license that allows it to ship immune globulin product to patient homes in any Tennessee county, when prescribed by patients' physicians.

c. What is the Medicare Intravenous Immune Globulin (IVIG) Demonstration Project? Does the applicant plan to participate?

Attached at the end of this letter is a short report to Congress from the Medicare program, describing that project. It was mandated by 2012 Federal legislation. It establishes a test program for reimbursing IVIG in any setting including the home setting. After the project was designed, HHS began soliciting Medicare patient (not provider) enrollment in 2014. The project is ongoing. The applicant will not accept Medicare patients, so none of the applicant's patients will be participating in that project.

3. Section B, Project Description, Item I

a. Please provide an overview of how home health infusion staff will be distributed in the 21 proposed county service area.

AxelaCare will employ nurses who have a reasonable drive time from their homes to the patients' homes, in each nurse's own judgment. The drive time from Memphis to all area counties is within norms for home health agencies (see Table Two on page 27 in the application). However, AxelaCare's priority will be to employ at least one nurse who lives in the Jackson area, in addition to having nursing staff who live in the Memphis area. This distribution will shorten nurse drive time to rural counties in the central and eastern parts of the service area.

b. If approved, please clarify if the applicant will subcontract any home health services associated with this application.

No. If approved, AxelaCare intends to deliver IVIG home nursing services to all area patients for whom AxelaCare immune globulin pharmaceuticals are prescribed by referring physicians.

c. What are the risks of a patient experiencing a reaction to a medication as a result of a first dose administered by a home health agency in the home?

The risks are the same wherever IVIG administration occurs. Please see "Side Effects of Intravenous Immune Globulins" (authored by Duhejk, Dicato, and Ries), attached at the end of this response letter. This clinical paper describes reported risks of IG therapy and how potential side effects are managed or avoided.

d. If a patient is new, typically are the first infusion doses administered in a controlled setting such as a hospital, MD office, clinic, etc.?

No. AxelaCare performs a pre-dose screening to determine if each patient is clinically appropriate to receive a first dose at home. AxelaCare's experience is that the majority of patients do qualify as low-risk, appropriate for the home setting. Patients who do not qualify receive a first dose in a monitored setting, rather than in their homes.

e. If RNs are needed to be specially trained in starting and managing home infusions, why does the applicant not require a nurse to have the Certified Registered Nurse Infusion Designation (CRNI) prior to employment?

AxelaCare uses only nurses who are highly skilled in infusion care before joining AxelaCare. Their skills are validated by AxelaCare's internal assessment program prior to their employment and deployment in the field. Many qualified nurses have never sought CRNI designation because it is very expensive and time-consuming to complete CRNI coursework and testing. However, once with AxelaCare, our nurses receive financial support from the company to seek and obtain CRNI designation.

f. Please provide an overview of the care exchange software and how is it different from other home health provider software.

The CareExchange technology and its uses and advantages were summarized on pages 14 and 15 of the application. For additional details, the applicant is attaching after this page an additional description of its advantages over other provider software, and copies of materials that are distributed to physicians and insurers describing some of its features.

g. It is noted the applicant appears to rely heavily on Axelacare's CareExchange Software to communicate real time with other providers while in the patient's home. Please indicate if rural internet coverage is adequate in all the proposed 21 Counties to use the web-based software.

The applicant cannot provide an analysis of rural internet coverage across every home in West Tennessee. But the applicant believes that internet is accessible in almost all parts of the service area. It is possible that there are a very small number of spots lacking coverage, and there is a possibility that a patient's home may be in such a spot. To allow for this, AxelaCare's CareExchange technology allows the RN to plan for it in advance. The forms and response sheets that would be downloaded "on site" in areas that are covered can be downloaded to the nurse's iPad before the home visit, from any spot where there is coverage. Forms and reports would then be completed manually in the patient's home, and would reside on the iPad until the nurse enters a covered zone on the return trip. At that point the iPad program would automatically upload all data, where it will be accessible to the referring physician 24/7.

CareExchange--The AxelaCare Advantage

After extended research, AxelaCare introduced its nurse-managed, iPad-based CareExchange technology in 2012. It was the first such system developed for physicians and their patients, and for the research community. As described in the CON application (pgs 14-15), this is an iPad-based software tool that the infusion nurse uses to:

(a) record critically important patient treatment and response data, including patient input, during the dosing session, and to
(b) make that data available via internet connection to the patient's physician in graphics, tables, and text formats both during and after the treatment session, and to
(c) create a growing database of significant importance to research studies.

The system is superior to that of other agencies known to the applicant; and the differences are significant.

First, the CareExchange software's data-gathering instruments were developed, and are maintained, using "best data" recommendations and requests from nationally recognized physician leaders and researchers in this complex field. AxelaCare believes that no other home health infusion company is as deeply involved with those clinical experts on an ongoing basis.

Second, the iPad-based information-gathering process is managed by a trained nurse, working on-site at the time of treatment, to gather important patient response data directly from the patient as well as from nursing observations. This real-time approach that incorporates both nurse and patient input, about measurable and felt responses to infusion, is more accurate, informative, and comprehensive than the old way -- which consisted of the team pharmacist interviewing the patient by telephone some time after the infusion visit, and the infusion nurse writing nursing reports from notes at some time after leaving the patient. This real-time, on-site, comprehensive information gathering and communication system is unique to CareExchange. The referring physician can access relevant data--both quantitative and "soft" information--in highly usable formats, at any time day or night, including during the infusion session itself.

Third, CareExchange captures data from a set of physical assessments of the patient at the time of the infusion session. The patient is asked to perform a set of simple physical tasks that have clinical meaning to reviewing physicians; and their performance of those tasks is quantified, recorded, and put into the physician's hands immediately to help inform treatment decisions. To AxelaCare's knowledge, only CareExchange has this important capability. It provides much-needed information for the physician.

For much more detail on the CareExchange technology and data sets, please review the additional CareExchange materials attached at the end of this response letter.

h. What diseases are currently approved by the FDA to be treated with IVIG?

Infusion products have different FDA-approved indications. Please see the chart below for some major examples. *See Supplemental Attachment 3i (especially pages 25-26) for a summary of eight clinical indications for which IVIG has been licensed by the FDA.*

Product	Manufacturer	Indications
Gammagard Liquid	Baxter Healthcare Corporation	• Primary Humoral Immunodeficiency • Multifocal Motor Neuropathy
Gammagard S/D	Baxter Healthcare Corporation	• Primary Humoral Immunodeficiency • B-cell Chronic Lymphocytic Leukemia • Immune Thrombocytopenic Purpura • Kawasaki syndrome
Gammaplex	Bio Products Laboratory	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Bivigam	Biotest Pharmaceuticals Corporation	• Primary Humoral Immunodeficiency
Carimune NF	CSL Behring AG	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Privigen	CSL Behring AG	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura
Gamunex-C Gammaked (Distributed by: Kedrion Biopharma)	Grifols Therapeutics, Inc.	• Primary Humoral Immunodeficiency • Immune Thrombocytopenic Purpura • Chronic Inflammatory Demyelinating Polyneuropathy
Flebogamma DIF 5% & 10%	Instituto Grifols, SA	• Primary Humoral Immunodeficiency
Octagam	Octapharma Pharmazeutika Produktionsges.m.b.H	• Primary Humoral Immunodeficiency

i. Are there any IVIG infusion therapies that are considered investigational by the FDA or commercial insurance carriers?

The applicant is not involved with any investigational studies. The applicant fulfills physician prescription of the infusion pharmaceuticals when a referral is made. Physicians currently prescribe IG (immune globulin) for both FDA-approved uses and "off-label" indications, which is both commonplace and desirable. Please refer to the excerpt below from another publication, and see the UnitedHealth IVIG Policy document at the end of this letter, which governs AxelaCare's use of IVIG for various complex patient conditions.

"Off-Label Indications:
The number of off-label uses for IG far exceeds that of labeled indications. Although IG has been proven useful for many disease states, the likelihood of manufacturers pursuing FDA approval for already treated indications is remote given the high cost of conducting trials without the benefit of increased marketing advantages. The sometimes tenuous and limited supply of IG, combined with the high costs of treatment, require best practice standards be used when deciding to treat with IG. Some diseases commonly treated off label with IVIG are Guillain-Barré syndrome, polymyositis, dermatomyositis, multifocal motor neuropathy, stiff person syndrome, relapsing-remitting multiple sclerosis and pemphigus.2 Anecdotal reports suggest IVIG is effective in treating autoimmune neutropenia, autoimmune hemolytic anemia, Evans syndrome and acquired hemophilia, especially when other therapeutic modalities fail.3
Indications Under Current Research
Many studies are currently being conducted to look at the efficacy of IG in non-FDA-approved indications. Three specific areas that are being explored, for which IG is not used as a standard of care, include Alzheimer's, secondary recurrent miscarriage and chronic regional pain syndrome.
Alzheimer's. IVIG appears to have promising effects for both reducing the risk of developing Alzheimer's, as well as improving the cognitive ability of those suffering from it. Results of a study presented at the International Alzheimer's Symposium in 2008 showed that the risk of developing Alzheimer's disease and related disorders (ADRD) may be reduced by about 40 percent in patients previously treated with IVIG.4
As of early 2009, several small clinical trials have shown promising results for treating Alzheimer's with IVIG.5 In March 2010, results of a Phase 2 clinical trial suggests that treatment with IVIG is associated with a reduction in ventricular enlargement rates and cognitive decline in patients with mild to moderate Alzheimer's. In the study, uninterrupted treatment with IVIG for 18 months was associated with about half the rate of ventricular enlargement

reflecting brain atrophy versus a placebo, along with better scores on neuropsychological testing. A pivotal Phase 3 study is now enrolling patients from 35 sites throughout the United States.6
Secondary recurrent miscarriage. Several clinical trials have been conducted to determine whether IVIG is an effective treatment for recurrent miscarriage. While clinical trials are still ongoing, one particular study consisted of a systematic review of randomized controlled trials, comparing all dosages of IVIG to a placebo or an active control. The study looked at eight trials involving 442 women that evaluated IVIG therapy used to treat recurrent miscarriage. The findings showed that, overall, IVIG did not significantly increase the odds ratio of live birth when compared with a placebo for treatment of recurrent miscarriage. However, there was a significant increase in live births following IVIG use in women with secondary recurrent miscarriage, while those with primary miscarriage did not experience the same benefit.7
Chronic regional pain syndrome (CRPS). Most recently, a small study found IVIG effective for alleviating CRPS, which causes chronic and often intractable pain, usually in the arm or leg, long after recovery from an illness. Researchers at the Pain Research Institute at the University of Liverpool in England administered a half gram of IVIG per kilogram of body weight to 13 people who had been suffering from CRPS between six and 30 months and who reported pain intensity of at least five on an 11-point scale for seven consecutive months. All had failed to achieve significant relief from other conventional treatments. After being treated with IVIG, five of the 12 subjects reported median pain scores at least two points lower, and three of the five reported pain scores at least 50 percent lower.8
Other diseases. There also are case reports and open label trials that show IVIG benefits some patients with rheumatoid arthritis, anti-neutrophil cytoplasmic antibody disorders, systemic sclerosis/scleroderma and Still's disease.3"

j. Please clarify if this proposed project involves any pain management infusion therapies.

The proposed agency will not serve diagnosed chronic pain patients. They are not IVIG cases. Minor pain management pharmaceuticals such as Tordol (a non-steroidal anti-inflammatory (NSAID) may on occasion be administered prior to administering IVIG, if the referring physician deems it to be needed; but this would be incidental to the IVIG therapy for which the patient was referred. AxelaCare is not a pain management provider and does not administer opioids.

4. Section B, Project Description, Item II.A

a. Please indicate the shelf life of the infusion dosages.

IG shelf live varies between manufacturers based on FDA approval; but it typically is between 24 and 36 months.

b. Does the applicant use common overnight carriers to deliver the product to patient homes?

In Tennessee, AxelaCare uses FedEx to deliver the product to patient homes.

c. Does the infusion patient sign for the delivery of the infusion dosage? If the patient is not available, what happens to the infusion dosage package?

AxelaCare requires proof of delivery by signature, either by the patient or a person designated by the patient. Some patients authorize the package to be left in the event no one is at home to sign for it; but this is strongly discouraged and rarely used.

d. How does the infusion nurse time patient visits to coincide with the infusion dose delivery?

Patients are ordered to receive the infusion at a set interval. When the nurse completes the current visit an approximate date is determined for the next infusion. Several days (4-7 days) prior to the tentative date, the pharmacy calls the patient and confirms/modifies the visit date and medication delivery date with the patient. The complete delivery should occur one to two days before the infusion. Once the delivery date is confirmed it is communicated to the nurse. The nurse verifies with the patient the day before the infusion that the delivery has occurred.

5. Section B, Project Description, Item II.C

a. Do commercial insurance carriers reimburse for non-FDA approved indications for IVIG?

Yes they do. Each commercial carrier does so in compliance with its corporate medical policies for approval and use of IG, based on diagnosis and supporting documentation. As an example, the applicant has attached UnitedHealth's policy document at the end of this response letter.

b. Table One on page 22 is noted. However, please provide the name of the West Tennessee Counties IVIG services are provided, and the subcontractor that Homechoice Health Services and Maxim Healthcare Services, Inc. contracts with.

Table Six-B in the application lists the counties that agencies are licensed to serve in the 21-county service area. Coram is licensed for all 21 counties. HomeChoice is licensed for Fayette, Hardeman, Haywood, Lauderdale, Shelby, and Tipton Counties (6). Maxim is licensed for Fayette, Hardeman, Haywood, Madison, Shelby, and Tipton Counties (6). Page 21 of the submitted application states correctly that both these agencies serve 6 counties; but Table One on page 22 mistakenly indicated that HomeChoice serves 4 counties. Attached following this page is a revised page 22R correcting that typographical error in Table One.

Maxim subcontracts with AxelaCare, for its home infusion patients. The applicant does not currently contract with HomeChoice and has no information on what agency contracts with HomeChoice.

c. When the applicant conducted the telephone survey of home health agencies in the proposed service area, did the applicant ask how many IVIG patients were being served by the three agencies listed in the table as being IVIG providers? If so, please provide.

This was not requested. Home health providers hold this level of information to be confidential and proprietary. It is not available to the applicant. Nor is it reported in the Joint Annual Reports. Even if an agency were willing to share this information, patient numbers would vary over time and would not be meaningful if provided on a "snapshot" basis at the time of a phone survey.

6. Section B, Project Description, Item V (Home Health Agency)
Does the applicant propose any branch offices?

No.

7. Section C. Need, Item 1 (Specific Criteria: Home Health Services)
It is noted the applicant addressed the Project Specific Criteria using the Guidelines for Growth, 2000 Edition. Please address the Project Specific Home Health Criteria according to the Tennessee State Health Plan 2014 Update. The update may be found at the following web-site:
http://www.tennessee.gov/assets/entities/hsda/attachments/FINAL_2014_SHP_Home_Health_Services_Criteria.pdf

Please see the attachment at the end of this supplemental response letter.

8. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)
Please indicate the physician referred projected number of cases by service category to be provided in the initial year of operation.

This is unavailable to the applicant. Physicians who have written letters of support for this project are not willing to project their potential IVIG referrals to AxelaCare, or the number of such patients they refer to other agencies or infusion sites. All patients served by AxelaCare will be solely for IVIG care. As you can see from UnitedHealth's clinically complex IG Policy document attached to this letter, it is not feasible to estimate cases by service category beyond the single category of IVIG.

9. Section C. Need, Item 1 (Specific Criteria: Home Health)- Item 6a & 6b
Your response in Table Three is noted. However, the expected Average Revenue/Patient of $5,750 in Year Two (2018) appears to be incorrect. Please revise.

This was a typographical error. The correct amount is $5,760, the same as stated in Year One of that Table Three. Attached following this page are revised pages 32R and 56R, both of which include Table Three.

10. Section C, Need, Item 6

The methodology of projecting the number of patients in Year One is unclear in the application. Please provide a brief simplified overview of the calculations, assumptions, referrals, etc. to project 45 patients in Year One.

Axelacare reviewed their Tennessee referrals and identified 127 referred IVIG patients Statewide. It was assumed that at least this level of referrals will continue, in an area of care with steeply increasing demand nationwide.* One-third of that number (43 patients) were projected to be coming from West Tennessee if this proposal is approved; and that was simply rounded up to 45 patients to allow for annual increases in demand. For the second year, a growth to 65 patients was assumed because where local marketing and community linkages are in place, AxelaCare typically sees a minimum of 5 to 6 new referrals per month.

**For example, the attached HHS report to Congress identifies (p. 7) a 55% increase in PIDD incidence -- a condition treated with IVIG -- with their Medicare enrollees over just a five-year period.)*

11. Section C. Economic Feasibility Item 1 (Project Cost Chart)

a. Your response is noted. However, please clarify if laptops, electronic record system, office equipment, portable electronic equipment, etc. has been accounted for in the Project Costs Chart.

The laptops are leased to AxelaCare and are shown in the Projected Data Chart's other expenses as a rental item. Office equipment and furnishings are provided in the Executive Suite lease arrangement. There is no other portable electronic equipment other than the I-pads.

b. Please clarify where $1,938.00 standard service fee retainer in the lease is accounted in the Project Costs Chart.

This retainer is two months' rent in advance. The lease agreement is year to year, so the Project Cost Chart was based on 12 months' rent at $969 per month. If the applicant moves to another Shelby County location (which requires no CON approval for a headquarters office) after one year, that retainer of two months' rent in advance is offset by no need to pay the last two months' rent. So the applicant requests that the Project Cost Chart not have to be revised to add $1,938 to Section B's lease outlay line.

12. Section C. Economic Feasibility Item 2 (Funding) and Item 10

a. It is noted the proposed project will be funded by the applicant's parent company. However, the financial balance sheets of UnitedHealth Group ending December 31, 2015 reflects total current assets of $21,639,000,000 and current liabilities of $42,898,000,000, and a current ratio of .50 to 1. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities. Please clarify if the applicant has the cash available to fund the proposed project. If so, please document.

Yes, as a Fortune 6 company with annual revenues that are projected to be in excess of $182 billion in 2016, AxelaCare's corporate parent -- United Health Group -- clearly has sufficient cash to cover the small, approximately $60,000 implementation costs associated with this application. Indeed, in the first quarter of 2016 alone, UHG and its corporate affiliates generated $3 billion in earnings from operations. For more information on UHG's financial wherewithal, please see the UHG earnings report attached at the end of this application.

b. The funding letter from AxelaCare Holding Inc. is noted. However, please clarify if the proposed project will be funded through a cash transfer through UnitedHealth Group Inc. or AxelaCare Holdings, Inc. If the proposed project will be funded through AxelaCare Holdings, Inc. please provide copies of the balance sheet and income statement from the most recent reporting period.

I think that the confusion is caused by the use of the term "parent company" in Mr. Collins' funding letter. AxelaCare Holdings, Inc. is the applicant's *immediate* parent company, but UnitedHealth Group Inc. is the applicant's *ultimate* parent company. The project funding will come from the ultimate parent company to the applicant *through* the immediate parent entity. Mr. Collins was authorized to affirm that. UnitedHealth Group's financial statements were provided in the application so it should not be necessary to submit additional financial statements for AxelaCare Holdings, Inc.

13. Section C. Economic Feasibility Item 4. (Historical Data Chart and Projected Data Chart)

a. Please clarify where the $99.00 monthly telecom/internet services as listed in the lease is accounted for in the Projected Data Chart for AxelaCare West Tennessee Nursing and Home office only.

Those are options in the lease. AxelaCare will not need the connectivity but is budgeting for phone service at $75 per month (based on company experience), as shown in the itemization of Other Expenses following the three Projected Data Charts.

b. The provision for charity care is noted at $5,184 in Year One in the Projected Data Chart for Axelacare West Tennessee Nursing and Home office only. This is less than the average gross patient charge of $5,760. Please clarify why the applicant will not at a minimum cover the average charge for one charity patient.

The charity care has been budgeted at the company average of 2% of gross revenues, which far exceeds the average of most home health agencies. This is a substantial commitment for a proposed nursing service that will operate at a loss. Please note that the 2015 JAR's of all three other agencies that provide home infusion care report zero ("0") charity care.

In addition, consider that the average charge of $5,760 will be the aggregation of many cases, some higher and some lower in gross charges. In practice, the charity care will cover charges for one or more of the lower-cost infusion cases.

c. The financial Assistance Program protocol in the attachment is noted. Please clarify if all charity care associated with this project must apply through the applicant's Financial Assistance Program.

Yes.

d. Please clarify if charity care entails only the waiver of co-insurance and/or deductible amounts.

No. A patient with drug coverage but not nursing coverage is eligible for discounts on nursing coverage as well as copays and deductibles.

e. Please clarify where the cost of automobiles, cell phones, and mileage are accounted for in the Projected Data Chart for Axelacare West Tennessee Nursing and Home office only.

Automobiles and cell phones are not provided by the applicant. Nurses use their own vehicles and are reimbursed for mileage. The latter was erroneously omitted from the "other costs" of the project; an estimate for that expense has been included in the revised Projected Data Charts and Other Expenses tables submitted in response to question 13f below.

f. The tables for "D9-Other Expenses" on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The categories you reference on the three Projected Data Charts are in fine print below the line D9. They are typographical errors, artifacts from a prior form, and should have been deleted before submittal. Attached after this page are revised pages 51R-53R, with those words removed from the three Charts, and revised page 54 with titles more closely matching the titles on the three Charts.

g. The Projected Data Chart-"Axelacare West Tennessee Pharmaceuticals Only" is noted. However, please clarify what the 10% in Year One and Year Two represents under F. Capital Expenditures.

That is also an artifact from a prior template that should not appear on the Chart. Revised page 53R submitted following this page corrects that typographical error.

h. The provision for charity care of $91,584 in Year One in the Projected Data Chart for Axelacare West Tennessee Consolidated is noted. However, this is less than the average gross patient charge of $101,760. Please clarify why the applicant will not at a minimum cover the average charge for one charity patient.

That charity care has been budgeted at the company average of 2% of gross revenues, which far exceeds the average of most home health agencies. This is a substantial commitment by agency standards. Please note that the 2015 JAR's of all three other agencies that provide home infusion care report zero ("0") charity care.

In addition, the average charge will be the aggregation of many cases, some higher and some lower in gross charges. In practice, the charity care will cover charges for one or more of the lower-cost infusion cases.

14. Section C, Economic Feasibility, Item 5
Table Eleven-A on page 55 is noted. However, the average net operating income after expenses per patients of -$3,217 and average net operating income after expenses, per visits of -$134.00 appears to be incorrect. Please revise.

Revised page 55R is attached following this page, with corrected and updated data.

15. Section C, Economic Feasibility, Item 6. A
Table Three on page 56 is noted. However, the expected Average Revenue/Patient of $5,750 appears to be incorrect. Please revise.

Please see the response to your question #9 above, and the revised page attached in response to that question.

16. Section C, Contribution to Orderly Development, Item 3
Please clarify if an RN/patient ratio of 2.5 RNs to 45 patients in Year One is adequate for a 21 County service area covering a geographical area of all of West Tennessee.

Such an RN/patient ratio is adequate. The projection of patients amounts to approximately 4 patients per month. With nurses based in Memphis and Jackson, this is a very reasonable expectation for nurse drive times, and the projected staffing is sufficient to serve those patients.

17. Section C, Contribution to Orderly Development, Item 7d

a. If possible, please provide the latest copy of the Axelacare's Specialty Pharmacy Program Inc.'s licensure survey and approved plans of correction.

Copies of the license and inspection survey are attached after this page.

b. The applicant is accredited by The Joint Commission. If approved, will this accreditation also include home health services?

Yes; once the applicant is licensed, the Joint Commission will be notified, and Tennessee will be added as an accredited site under the existing accreditation.

18. Proof of Publication

Please provide copies of the publication of intent of the required 4 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 21 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication have not all been received from the newspapers. They will be submitted under separate cover.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn
Consultant

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

SUPPLEMENTAL ATTACHMENTS

Question	Attachment
2e.	HHS Report to Congress on IVIG Demonstration Project
3c.	Side Effects of Intravenous Immune Globulin
3i.	UnitedHealth IVIG Policy Document
7.	Response to State Health Plan's Current CON Criteria for Home Health Agencies
12.	UnitedHealth Group Earnings Report, Q1 2016
17.	AxelaCare Health Solutions -- Licensure Information

2e. HHS Report to Congress on IVIG Demonstration Project

Evaluation of the Medicare Patient Intravenous Immunoglobulin Demonstration Project: Interim Report to Congress

U.S. Department of Health and Human Services

Introduction

Section 101 of H.R. 1845 Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012 (Medicare IVIG Access Act), Public Law 112-242, mandates the establishment, implementation, and evaluation of a three-year Medicare Patient Intravenous Immunoglobulin (IVIG) Access Demonstration Project under Part B of title XVIII of the Social Security Act. The demonstration project will voluntarily enroll up to 4,000 Medicare beneficiaries who have been diagnosed with Primary Immunodeficiency Diseases. Under the demonstration, Medicare will provide to suppliers of IVIG a bundled payment under Part B for items and services necessary to administer IVIG in-home to enrolled beneficiaries who are not otherwise homebound or receiving home health care benefits.

The Act also requires a report to Congress that provides interim evaluation findings on the impact of the demonstration project on Medicare beneficiaries' access to items and services needed for the in-home administration of IVIG. This interim report fulfills the statutory requirement.

Background

Primary Immunodeficiency Diseases (PIDD) are a group of conditions that are triggered by genetic defects which cause a lack of and/or impairment of antibody function, resulting in the body's immune system not being able to function effectively. Immunoglobulin (IG) therapy is used to temporarily replace some of the antibodies (immunoglobulins) that are missing or not working properly in people with PIDD, and it is the treatment of choice for Medicare beneficiaries with this diagnosis. The goal of IG therapy is to use IG obtained from normal donor plasma to keep enough antibodies in the blood of patients with PIDD to fight off bacteria and viruses. There are two forms of IG therapy: intravenous immunoglobulin (IVIG) and subcutaneous immunoglobulin (SCIG).

In 2006, the U.S. Food and Drug Administration (FDA) approved an SCIG product for the treatment of patients with PIDD. Patients may self-administer this product at home using an infusion pump. Traditional fee-for-service (FFS) Medicare covers the SCIG product and the infusion pump needed at home under the Medicare durable medical equipment (DME) benefit. Section 642 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, amended section 1861 of the Social Security Act, to require Medicare Part B coverage of IVIG for the treatment of PIDD in the home. The statute only covers IVIG and did not cover any of the items and services needed to administer the drug. The specific items and services are the supplies and in-home nursing services necessary to inject the drug intravenously. These items and services for administering the drug may be covered if the person is homebound or otherwise receiving services under a Medicare home health episode of care. As a result, many beneficiaries receive IVIG at their doctor's office or in an outpatient hospital setting, or they elect to receive the IG therapy subcutaneously because the items needed to administer SCIG in-home are covered by Medicare.

Under the Medicare Patient IVIG Access Demonstration, by paying for the items and services needed to administer the IVIG drug in-home, Medicare will enable beneficiaries and their physicians to have greater flexibility in choosing the option that is most appropriate for the

beneficiary. With the exception of coverage of these items and services, no other aspects of Medicare coverage for IVIG (e.g., drugs approved for coverage or PIDD diagnoses covered) will change under the demonstration.

Implementation of the Medicare Patient IVIG Demonstration Project

The Centers for Medicare & Medicaid Services (CMS) developed, as required by the Medicare IVIG Access Act, a bundled per-visit amount to be paid to any Medicare supplier that is able to provide the IVIG drug and the professional services needed for administration. The supplier is also able to provide the professional services either using their own staff or through a separate contract. All staff administering the drug must meet their licensure requirements.

Eligible suppliers who submit claims for the drug and administration of the drug on a single claim form to a Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) will receive the bundled payment for the supplies and services to administer the drug in addition to the payment for the drug which is currently covered under the Medicare benefit. Home health agencies are not eligible to be paid under the demonstration for the administration of the IVIG although they may contract with suppliers in their area to provide professional services. In such situations, the supplier would receive the demonstration payment and reimburse the home health agency directly in accordance with their contract.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of intravenous immunoglobulin was based on the national per visit low-utilization payment (LUPA) amount under the prospective payment system for home health services established under section 1895 of the Social Security Act. The demonstration bundled payment that covers medically necessary items and services needed for the in-home administration of IVIG is based on the LUPA rate used in the Medicare Home Health Prospective Payment System. The LUPA rate is made for beneficiaries who require four or fewer visits during a 60-day home health episode.

A home health episode with four or fewer visits is paid the national per visit amount by discipline adjusted by the appropriate wage index based on the site of service of the beneficiary. Such episodes of four or fewer visits are paid the wage-adjusted per visit amount for each of the visits rendered instead of the full episode amount. The national per visit amounts by discipline (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services) are updated and published annually by the applicable market basket for each visit type.

Per the Act, the bundled payment amount for items and services needed for the in-home administration of IVIG includes infusion services provided by a skilled nurse. Therefore, the bundled payment is based on the LUPA for skilled nursing only because the services of the other LUPA disciplines are not required for this demonstration. A total per-visit bundled payment of $300 in 2014 was initially calculated. This payment rate is based on the full skilled nursing LUPA for the first 90 minutes of the infusion ($120) and 50% of the LUPA for each hour thereafter for an average 4.5 hour infusion [(100% x $120) + (50% x 3 hours x $120)]. The payment rate is to be revised and updated annually based on the LUPA rate. The payment rate is also subject to

sequestration. In 2015, the bundled payment rate was $319.23. This service is subject to coinsurance and deductibles similar to other Part B services provided in the doctor's office.

Prior to finalizing the design of the demonstration, CMS reached out to relevant stakeholders, including beneficiary advocacy groups, suppliers, and professional societies among others. In addition to in-person meetings, CMS hosted several Open Door conference calls and webinars to increase awareness of, and obtain input on, the demonstration project.

CMS contracted with NHIC, Corp., one of the Medicare Administrative Contractors, to perform the demonstration implementation activities. Tasks included outreach and education, enrollment application processing, handling the demonstration hotline, resolving denied demonstration claims, and reporting. Demonstration claims are payable if the demonstration code (Q2052) is billed with the drug (J code) on the same claim. There are also requirements related to dates for each of the line items on the claim. When claims are not submitted in accordance with the specified requirements, claims may be denied. NHIC Corp. reviews all denied claims and if needed, works with the supplier to resolve any problems. Claims that are denied due to submission errors may be resubmitted. NHIC engaged in targeted outreach to physicians who treat PIDD beneficiaries, beneficiary advocacy groups and IG suppliers. NHIC conducted public dissemination activities to increase awareness and facilitate demonstration enrollment.

To be eligible to enroll in the demonstration project, traditional Medicare must be the beneficiaries' primary insurance, thereby excluding beneficiaries (e.g. some working aged beneficiaries) for whom alternative insurance is the primary payer. Beneficiaries must also: a) have current coverage under the Medicare fee-for-service program; b) have coverage under Medicare Part B; c) have a diagnosis of PIDD; d) submit a completed application with physician approval; and e) not be currently receiving Medicare home health services. For the purposes of the demonstration, the following Medicare covered PIDD diagnoses were included: common variable immunodeficiency, selective immunoglobulin M (IgM) deficiency, Wiskott-Aldrich syndrome, congenital hypogammaglobulemia, and immunodeficiency with increased IgM.

NHIC conducted an analysis of Medicare claims to identify all Medicare fee-for-service beneficiaries with a PIDD diagnosis who had been treated with IVIG across the country. Based on this analysis, information about the demonstration and application letters were mailed out to 9,216 potentially eligible beneficiaries with PIDD who had claims for IG treatment in August, 2014 and, again, in January 2015. Letters were also sent to professional societies and providers treating beneficiaries for PIDD.

The Medicare Patient IVIG Demonstration Project was announced via twitter and on the CMS website. CMS sent out the following tweet on August 5, 2014 announcing the demonstration 'Interested in #IVIG? Announced #Medicare Intravenous Immune Globulin Demonstration 8/5, info: http://go.cms.gov/1s838K2 #careinnovation'. CMS also posted information about the demonstration on the CMS website at https://innovation.cms.gov/initiatives/IVIG/.

The beneficiary application mailings began August 8, 2014 with an initial September 15, 2015 deadline. Bundled payment for approved beneficiary IVIG services started on October 1, 2014. Beneficiary applications are now accepted on a rolling basis as long as space is available.

In October 2014, 352 beneficiaries had enrolled in the program. Due to the low initial enrollment in the demonstration project, targeted outreach was done in order to increase enrollment. In January 2015, NHIC mailed out a second letter and application to beneficiaries who had not applied to inform them that there were still openings in the demonstration. This targeted mailing resulted in an increase in the number of inquiries to the designated demonstration hotline number and an increase in enrollment. By August 1, 2015, the demonstration project enrollment had increased to 872 beneficiaries.

As of August 1, 2015, 9.5 percent (n=872) of the 9,216 eligible Medicare beneficiaries had submitted completed application forms and were enrolled in the demonstration project. Monthly growth has averaged around 44 new enrollees per month (range 30-84) reflecting a mix of those new to the Medicare program, beneficiaries newly diagnosed with PIDD, and those just learning about the demonstration or only now interested in possibly switching to in-home administration of the IVIG drug. Among those enrolled, about fifty percent (449 beneficiaries) have used the demonstration benefit based on the claims submitted and paid under the demonstration through August 7, 2015. Additionally, 235 suppliers have submitted demonstration claims.

Evaluation of the Medicare Patient IVIG Demonstration Project

The Medicare IVIG Access Act requires an interim and a final evaluation report due no later than one year after the demonstration project ends, to be submitted to Congress. The interim report is to contain an evaluation of the impact of the demonstration on access for Medicare beneficiaries to items and services needed for the in-home administration of IVIG. The final report will contain a final evaluation of the impact on access to IVIG items and services, as well as an analysis of the appropriateness of implementing a new methodology for payment for IVIG in all care settings, and an update to the 2007 report by the Assistant Secretary for Planning and Evaluation (ASPE) of the Department of Health and Human Services (HHS), entitled *Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immunoglobulin Intravenous*.

CMS awarded a contract to Dobson, DaVanzo & Associates, LLC, to conduct the evaluation activities. The assessment of the impact on access to IVIG items and services, as well as the analysis of the appropriateness of implementing a new payment methodology, will include both a qualitative (beneficiary surveys and provider interviews) and a quantitative (Medicare claims) analytic approach. The update of the ASPE report will also include both qualitative and quantitative research activities. These analyses will be described in the final report.

Because the demonstration has operated for less than a year, there is insufficient demonstration claims experience available to date for analysis, thus, analytic findings concerning the demonstration's impact on Medicare beneficiary access to items and services needed for the in-home administration of IVIG are not included in the interim report. However, this report provides information on the implementation experience to date and a descriptive analysis of Medicare claims information for the demonstration baseline in 2014. Medicare Part A and B claims for beneficiaries with a PIDD diagnosis (consistent with the ICD-9 codes eligible for demonstration enrollment) and the receipt of IVIG (drug code and infusion administration) on the same day for the year 2014 were used for the baseline analysis. The demonstration claims for the

three months (October-December, 2014) showed low demonstration enrollment, and with the claims lag time provided insufficient information to draw preliminary conclusions.

The implementation experience findings were based on the review and analysis of NHIC's reports and hotline logs. Beneficiary surveys and supplier interviews were not included in this interim RTC. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled), suppliers, and other stakeholders in the final RTC. These activities are expected to be initiated in 2016.

The purpose of the baseline analysis is to describe the demographics and patterns of IVIG utilization among beneficiaries with PIDD prior to the demonstration project.

Key findings related to implementation experience indicate that:

- Enrollment in the demonstration is lower than anticipated with 872 enrolled as of August 01, 2015;
- Claims submitted for demonstration services by enrolled participants (n=449) are lower than anticipated as of August 01, 2015;
- Some beneficiaries appear to be enrolling in the demonstration just to reserve spots "in case" they want it—concerned about potential future limits;
- It has not been difficult to find suppliers nationwide; and
- Some beneficiaries are confused about the demonstration benefit offered.

Key findings from the baseline analyses illustrated in Tables 1 and 2 below include:

- There was approximately a 60 percent growth rate in Medicare beneficiaries with PIDD receiving IVIG treatment over the past 5 years;
- The average age of Medicare beneficiaries with PIDD who received IVIG was 68 years old in the year 2014, with over half (59 percent) aged 65 to 79 years;
- Twenty-five percent of the Medicare beneficiaries with PIDD in the year 2014 were beneficiaries younger than 65 years old;
- In 2014, the majority of the PIDD population who received IVIG was white (95 percent) and female (68 percent); and
- In 2014, most of the Medicare beneficiaries with PIDD who were treated with IVIG received their IG treatment in an outpatient facility setting including hospitals, outpatient departments, and infusion suites (66 percent). The rest received IVIG services in a doctor's office.

Table 1. Medicare PIDD growth from 2010 through 2014

Year	2010	2011	2012	2013	2014
Medicare beneficiaries with PIDD	15,473	17,579	20,097	22,755	23,970
Medicare beneficiaries with PIDD receiving IVIG treatment	5,723	6,468	7,496	8,483	9,150

Table 2. Demographics in baseline year 2014.

Variables	Medicare beneficiaries with PIDD on IVIG in 2014	
Age	Beneficiaries	Percent
<65	2,303	25%
65-69	2,046	22%
70-74	2,010	22%
75-79	1,361	15%
80-84	815	9%
85+	615	7%
Total	9,150	100%
Gender	Beneficiaries	Percent
Male	2,953	32%
Female	6,197	68%
Total	9,150	100%
Race	Beneficiaries	Percent
Unknown	104	1%
White	8,684	95%
Black	164	2%
Other	92	1%
Asian	31	0%
Hispanic	53	1%
North American Native	22	0%
Total	9,150	100%
Original reason for Medicare Entitlement - Disability benefit	Beneficiaries	Percent
Age less than 65 years	2,262	24.7%
Age 65 and older	1,329	14.5%
Total	3,591	39.2%

Overall, the baseline data show that the Medicare beneficiaries with PIDD on IVIG are more likely to be younger (66% younger than 74 years of age), female (68%), white (95%) and non-disabled (75%).

Limitations of the Evaluation

This interim report has several limitations. The low initial enrollment of beneficiaries into the demonstration project makes it difficult to present any findings at this time. Additionally, Medicare claims data for the time period covered in the report (the first ten months of the demonstration) are not yet available due to the lag in obtaining claims data, so an analysis based on demonstration Medicare claims could not be included.

Conclusion

In summary, the demonstration enrollment is voluntary. Presently, beneficiaries have the option to receive the IVIG drug and services in an outpatient setting, a physician's office, an infusion center, or an in-home setting. Given the limited 10-month demonstration experience and low enrollment uptake to date, the interim report does not include an assessment of the impact of the demonstration on beneficiaries' access to items and services needed for the in-home administration of IVIG. The evaluation plan does include conducting and reporting findings from beneficiary surveys (targeting both beneficiaries who are enrolled in the demonstration and those who are not enrolled).

Future recommendations on beneficiaries' access to items and services for in home administration of IVIG will be provided in the final evaluation report. In the meantime, CMS will continue its outreach efforts to beneficiaries and suppliers about the demonstration. This will include targeted outreach focused on non-enrolled beneficiaries eligible for the demonstration via mailings (i.e., a personal letter informing them about the demonstration on an annual basis). The final report to Congress will provide findings based on the full three years of the demonstration project.

3c. Side Effects of Intravenous Immune Globulin

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Side-effects of intravenous immune globulins

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SUMMARY

Intravenous immune globulin (IVIG) preparations are efficacious and safe products in use worldwide. Although rare, side-effects of IVIG may be serious, even life-threatening, and clinicians should be aware of their potential occurrence. This article summarizes most of the adverse experiences with IVIG reported in the literature since its introduction into clinical practice almost 15 years ago.

Keywords IVIG side-effects management prevention

INTRODUCTION

The clinical benefit of immune globulin prophylaxis in patients with primary antibody deficiency syndromes has been clearly established. In the past, replacement therapy was provided through intramuscular injections. In the early 1980s, highly purified monomeric suspensions of IgG for intravenous use became available and more than 10 commercial preparations of intravenous immune globulin (IVIG) are now at the disposal of the clinician. The indications for administration of IVIG have been enlarged to include transitory primary antibody deficiencies (such as low birth-weight premature babies), secondary hypogammaglobulinaemic states [as in chronic lymphatic leukaemia (CLL) or multiple myeloma], and conditions with increased susceptibility to infections (such as bone marrow transplant or the post-surgery period). In addition to its efficacy as replacement therapy, IVIG now has well-established therapeutic applications in some haematological and autoimmune diseases: IVIG preparations are used successfully in immune thrombocytopenic purpura (ITP), in Kawasaki disease, and for some desperate diseases for which there is no other efficient treatment [reviewed in refs 1 and 2]. The mechanisms of action of IVIG in these conditions, although not yet fully determined, include a reticulo-endothelial blockade, an immunomodulatory effect (by supplying anti-idiotype antibodies), and an anti-inflammatory action.

This growing usage has increased the need for high quality immune globulin products and, indeed, high-dose IVIG can be administered with only mild, self-limited side-effects. This paper reviews the most frequent adverse reactions reported with IVIG therapy from the time of its introduction into the clinic. Possible underlying causes of these reactions and their current management are described briefly.

SIDE-EFFECTS OF IVIG

The side-effects of IVIG can be separated into adverse reactions due to the relative 'impurity' of the commercial preparations (viruses, soluble substances or immunoglobulins other than IgG) and undesirable effects of their active component, the IgG. However, some of the mechanisms underlying these side-effects are speculative and probably complex. The side-effects are enumerated here according to their major manifestations, irrespective of their putative cause.

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Generalized reactions

The incidence of generalized reactions occurring during and/or after the administration of IVIG is reported to be in the range of 1–15 % (usually less than 5%). Most of them begin 30–60 min after the onset of the infusion; they are often mild, self-limited and include the following: pyrogenic reactions; minor systemic reactions such as headache, myalgia, fever, chills, low back pain, nausea and/or vomiting; vasomotor and cardiovascular manifestations marked by changes in blood pressure and tachycardia—these may be related to occasional reports of shortness of breath and chest tightness.

These reactions are generally considered to be due to aggregated immunoglobulin molecules which cause the complement system to be activated. They may be due to antigen–antibody reactions as well, or to possible contaminants or even stabilizers that may have been used during the manufacturing process. Frequently, these manifestations can be managed quite easily, sometimes just by reducing the rate of IVIG infusion or stopping it.

Far less frequently, the onset of symptoms of a generalized reaction is delayed until a few days after IVIG infusion, suggesting a type III allergic reaction [3].

Hypersensitivity and anaphylactic reactions

Severe and even fatal anaphylactoid reactions [4,5] may occur during IVIG treatment in patients with IgA deficiency; the appearance of anaphylactic shock is correlated with the presence of anti-IgA antibodies of the IgG and IgE isotypes in the patient's serum [5]. Among hypogammaglobulinaemic patients, those with combined subclass deficiency (for example, IgG2 and IgA deficiency) are more likely to develop this complication. Patients with autoimmune diseases have an increased prevalence of selective IgA deficiency when compared to normal blood donors (1/50 in systemic lupus erythematosus

versus 1/700 in a normal Caucasian population). Furthermore, anti-IgA antibodies seem to be more frequent in those IgA-deficient subjects with autoimmune diseases [6].

Seriously ill patients with a compromised cardiac function may be at increased risk of vasomotor cardiac complications, manifested by elevated blood pressure and/or cardiac failure. The kallikrein activity of some IVIG preparations has been incriminated as contributing to these adverse vasomotor reactions. Moreover, the volume of fluid delivered with IVIG (700 ml with standard preparations) is intolerable in a subset of fluid-restricted patients with congestive disease, especially at a high infusion rate.

Haemolytic anaemia

Two cases of acute Coombs-positive haemolytic anaemia developing during IVIG treatment have been published. The patients, a 30-year-old man and a 9-month-old child, were treated for ITP and Kawasaki disease, respectively [7,8]. In both cases, haemolysis mediated by antibodies to blood-group antigen could be demonstrated. When high doses of IVIG are infused, their isoagglutinin content can be sufficient to explain a Coombs-positive haemolytic anaemia. Furthermore, decreased haptoglobin levels and mild reticulocytosis have been described in normal volunteers receiving IVIG, but without any change in haemoglobin level, suggesting that clinically insignificant, well-compensated haemolysis may occur during IVIG treatment [9].

Viral contamination

Several papers published between 1983 and 1987 reported clusters of non-A, non-B hepatitis after IVIG treatment [10–13]. Hepatitis seemed to run a more severe course in hypogammaglobulinaemic patients with cirrhosis, and death by hepatic failure resulted in some of them. The mechanisms whereby some preparations (and not others during the same period) could be infectious remain unclear. They could include problems with the method of manufacture, either an isolated error in production or a basic defect in the manufacturing procedure, or an insufficient level of specific neutralizing antibody in the source plasma, allowing the presence of an excessive amount of virus. Finally, there is the possibility that the infection could be the result of non-parenteral transmission of the so-called non-A, non-B hepatitis [14].

It now appears clear that anti-hepatitis C positivity of blood products varies, depending on the country of origin of plasma donation [15]. Donors that test antibody-positive are systematically excluded. In February 1994, Baxter Healthcare Corporation, Glendale, California, USA instituted a worldwide recall of Gammagard®, its brand of IVIG, because of reports of some ten cases of possible transmission of hepatitis C. The coming months should clarify this issue and its extent. The production process for this IVIG preparation includes a chromatography procedure without any further chemical step of inactivation. As of this writing, other IVIG products currently in use have not been incriminated in hepatitis C transmission. Additional steps used in the production process of most other IVIG preparations include adjustment to pH 4, or the use of propionic acid or solvent detergent. At present, it seems cautious to use only IVIG products that have been prepared with an additional inactivation procedure.

No case of human immunodeficiency virus (HIV) seroconversion has yet been ascribed to the administration of IVIG. Furthermore, experiments in which large amounts of HIV were added to plasma before fractionation indicate that HIV is successfully eliminated during IVIG preparation.

Hepatitis B virus has not been detected in IVIG batches and the risk of its transmission is also considered negligible.

Neurological complications

As noted previously, headache is commonly reported by patients receiving IVIG; this symptom is efficiently palliated by antalgic and/or anti-histaminic drugs. Acute aseptic meningitis has been reported as a cause of recurrent IVIG-associated headaches. A 7-year-old boy treated for ITP presented with severe headache, vomiting, fever and meningism a few hours after his second infusion of IVIG [16]. A similar episode has been reported in a 2-year-old Japanese girl also treated for ITP. Seven days after IVIG infusions she experienced the same symptoms as the child just described, which were also attributed to an aseptic meningitis [17]. Two other cases have been reported in the literature [18,19]. The mechanism of this reaction remains unclear; several cases of aseptic meningitis have been associated with the use of drugs such as isoniazid and sulphamethizole or in patients with systemic lupus erythematosus taking anti-inflammatory agents.

Recently, a case of recurrent migraine after IVIG therapy has been described, suggested by the typical symptoms at presentation and the efficient prevention by propanolol before subsequent IVIG infusions. Again, the mechanism is difficult to explain [20].

Stroke as a side-effect of IVIG treatment will be discussed later.

Renal complications

Renal failure related to IVIG treatment has been reported in eight cases [21–24]. When it occurred, the best evidence for a cause–effect relationship was the close temporal association between infusion of the drug and the onset of clinical (oliguria) and biological symptoms, as well as the patients' return to pretreatment creatinine levels after stopping the drug, with the exception of a young woman who was haemodialysed and subsequently received a transplant. Renal biopsy was performed in four patients and some pathological features in three of the cases suggested a high solute load-induced damage of the proximal tubule, similar to that associated with the use of dextran or mannitol. Immunoglobulins themselves (especially large aggregates), or more likely, some component of the preparations (such as sucrose) could be responsible for this injury. The fourth case was a 39-year-old woman with mixed cryoglobulinaemia associated with a lymphoma, who had been treated specifically for hypogammaglobulinaemia and recurrent infections. The mechanism of renal damage in this case differs from the previous cases: this patient developed acute, severe, mixed cryoglobulinaemic nephropathy with evidence of antigen–antibody complex deposition after a single infusion of IVIG [24]. However, most of these patients presented with impairment of their renal function before the episode of acute degradation; IVIG treatment probably just contributed to the deterioration in renal function. Support for this conclusion comes from observations that elevated serum creatinine levels occur in patients with glomerulonephritis who receive IVIG for nephrotic syndromes

[25]. This should draw attention to the importance of screening for impaired renal function before IVIG therapy is initiated. In addition, the report of the case of acute cryoglobulinaemic renal failure after IVIG can serve as a caution against this potential complication in patients with B cell neoplasm and demonstrable serum rheumatoid factor activity.

Thrombotic events

Woodruff *et al.* reported four cases of fatal stroke in elderly patients (62–83 years old), all receiving IVIG for ITP [26]. The authors postulated that IVIG infusion could be responsible for an enhancement of adenosine triphosphate release from platelets, favouring their aggregation, as suggested by *in vitro* aggregometry studies, but these data were not confirmed by another group [27]. In those cases with ITP, the rise in platelet count during IVIG treatment could have played a role in the thrombotic event.

Recently, Reinhart & Berchtold studied the effect of high-dose IVIG on blood rheology both *in vitro* and *in vivo* [28]. Their data show that the rise in viscosity occurring after IVIG therapy can significantly impair blood flow; for this reason IVIG infusions might be sufficient to generate myocardial infarction or stroke in predisposed patients, especially elderly patients at risk of cardiovascular and thromboembolic events. However, few severe thrombotic episodes have been observed with IVIG therapy and when mentioned in case reports, the aetiological link between the treatment and frequent events in old and severely ill patients is not obvious.

Contamination of IVIG batches

Immunologically active proteins. The levels of soluble class II molecules (sHLA-DR, -DQ and -DP) in IVIG preparations appear to exceed those found in the plasma of healthy individuals, suggesting a concentration process [29]; in contrast, HLA class I molecules (A,B,C) are not detectable. Based on the total dosage of IVIG per infusion, the contaminating sHLA class II molecules may become immunogenic.

Significant levels of soluble CD4 and CD8 molecules have been found in some commercial preparations [30]. Seventeen of these were tested by enzyme-linked immunosorbent assays for the presence of proteins and cytokines such as interferon-γ (IFN-γ), tumour necrosis factor, interleukin-1 (IL-1), sIL-2 and sIL-4. Of the substances studied, only IFN-γ was present at measurable concentrations [31]. The clinical relevance of these observations remains unclear.

Anticytoplasmic antigens (ANCA). One case of uveitis has been reported in a 9-year-old hypogammaglobulinaemic patient, which was attributed to a localized vasculitis [32]. Cytoplasmic ANCA activity was detected in IVIG batches and was proposed as the cause of the vasculitis. However, the causative role for ANCA in vasculitis remains unproven [33]. Attempts to transfer the disease to animals by the same mechanism have failed. Moreover, a transient peak in serum ANCA activity has been noted after IVIG infusion, attributed to displacement of ANCA from tissue sites [34]. The young patient in the case report might have had an underlying localized vasculitis.

Miscellaneous side-effects

Many side-effects of IVIG are in the literature as sporadic case reports. Generally, the assessment of a real cause–effect relationship is sustained by a temporal association to the infusion and the absence of other obvious aetiological agents. Most of the time, no clear physiopathogenic explanation can be given.

Alopecia. Three cases of alopecia developing after infusion of IVIG have been reported [35]. The three women (aged 19, 42 and 61) were being treated for ITP and complained of diffuse alopecia up to 4 weeks after treatment. Their hair regrew within the 4 weeks following the withdrawal of IVIG. Two more cases have been reported by the IVIG manufacturers. An immunological basis for alopecia is possible, despite the negativity of immunofluorescence studies performed on the scalp biopsies of two of these patients.

Hypothermia. We saw one case of transitory hypothermia (to 35°C) in a 59-year-old CLL patient after each IVIG infusion. The pathogenesis of this observation remains obscure.

MANAGEMENT AND PREVENTION OF IVIG SIDE-EFFECTS

The management of the side-effects of IVIG is symptomatic and, in view of their mildness, they do not necessitate any aggressive treatment in most cases. Depending on the particular manifestation, drugs palliating the symptoms are antalgic, anti-pyretic, or anti-histaminic drugs; non-steroidal, anti-inflammatory agents; and/or low-dose corticosteroids.

Most adverse reactions to IVIG treatment could be reduced in three main ways: assuring the maximal purification of the product, screening the patient for factors predisposing to complications and respecting some rules of administration.

Purification of IVIG

One batch of IVIG results from processing the plasma of 3000–15 000 donors, all of whom are currently screened for hepatitis B and C, undergo HIV serology and measurement of transaminase levels. Commercial IVIG products are prepared from pooled plasma by the cold-ethanol fractionation technique based on Cohn's procedure and now in world-wide use. Once the plasma fraction II has been obtained, the immunoglobulins are stabilized by substances such as β-propionolactone. This procedure of cold-ethanol fractionation contributes to inactivation of viruses which might be present in the plasma pool, despite meticulous donor selection and the use of sensitive screening procedures. Moreover, β-propionolactone also has virucidal properties.

In addition, some manufacturers currently include a step of inactivation of lipid-enveloped viruses by a solvent detergent technique in the processing. This, concurrent with such measures as lowering the pH, raising the temperature, and increasing the incubation time during the production of IVIG, renders these products free of any major viral transmission.

The composition of each IVIG speciality is not exactly the same: they may differ in IgG subclass levels and IgA contaminants. Preparations containing very low levels of IgA should be selected for patients who present with serum anti-IgA antibodies or in emergency situations where this information cannot be obtained before IVIG treatment.

Screening of the patient

Most of the severe reactions to IVIG have been observed in patients with anti-IgA antibodies. This eventuality should be

assessed by systematic screening before any instauration of treatment, particularly in patients with hypogammaglobulinaemia or autoimmune diseases [36].

As noted earlier, the presence of rheumatoid factor activity (especially in patients with B lymphoma) or renal impairment should be investigated in any candidate for IVIG treatment.

Drug administration

Rate of infusion. The rate of IVIG infusions should be low at the beginning and increased every 15–30 min, based on the patient's tolerance. Infusion of a standard dose (e.g. 400 mg/kg) may take up to 8 h in some patients. In most cases, symptoms such as chills, fever and headache during infusion may be alleviated by lowering the rate of infusion or briefly stopping it. A phase I rate-escalation study was conducted recently in patients undergoing bone marrow transplantation and receiving 500 mg/kg of IVIG per week prophylactically, to determine the minimal period of infusion of concentrated IVIG that was well tolerated [37]. After a first infusion over a 6-h period, the 40 patients were randomized to receive the same treatment over a period of 2, 3, 4 or 5 h. The conclusion was that IVIG could be infused over a 3-h period with good tolerance, but a faster rate of infusion was poorly tolerated. This rule should be respected, particularly in patients at risk of complications (those with multi-organ failure, previous severe reactions, etc.).

Premedication. For patients with repeated reactions unresponsive to reducing the infusion rate, premedication with hydrocortisone (100 mg intravenously) or an antihistaminic drug can be considered and is generally efficacious.

CONCLUSIONS

IVIG preparations are some of the safest biological products available. Although severe adverse experiences have been reported, they are all largely anecdotal. Besides, the aetiological role of IVIG in their pathogenesis is rarely unequivocal.

The benefits of IVIG have been described for a growing number of conditions where immunoregulatory disorders are suspected and for which satisfactory alternative treatment is lacking. This harmless drug has been 'tried' and isolated therapeutic responses that are occasionally dramatic and plausible have been reported, while failures are forgotten. In contrast to the preventive indications study, few randomized placebo-controlled trials have been conducted to assess the real therapeutic impact of IVIG in conditions such as rare vasculitis, demyelinating neuropathies or severe epilepsy, which require multicentre studies. Simultaneously, the specific side-effects attributed to IVIG in those special indications could be appreciated.

To date, and because patients can be screened for anti-IgA antibodies, IVIG can be administered very safely with minimal reactions. However, this currently very expensive form of therapy should still be restricted to adequately established indications.

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7. Response to State Health Plan's Current CON Criteria for Home Health Agencies

AxelaCare Health Resources--CN 1606-022
Supplemental Response to Application Section C.Need, Item 1
(Specific Criteria: Home Health)

Standards and Criteria--State Health Plan

1. **Determination of Need: In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. This 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed Service Area.**

2. The need for home health services should be projected three years from the latest available year of final JAR data.

3. The use rate of existing home health agencies in each county of the Service Area will be determined by examining the latest utilization rate as calculated from the JARs of existing home health agencies in the Service Area. Based on the number of patients served by home health agencies in the Service Area, an estimation will be made as to how many patients could be served in the future.

In the table on page 29 of the CON application, TDOH projected the service area need/surplus in conformity to criteria 1 and 3 above, but used its customary 4-year (2020) projection horizon for calculating need as specified in an earlier version of these Guidelines.

At the end of this response, the applicant is submitting a Supplemental Table One, a revised Need projection that uses the 2018 population projections of the TDOH to comply with the 3-year planning horizon now specified in the current State Plan. The table indicates a surplus capacity of 15,122 patients, based on the 1.5% criterion and the most recent (2015) JAR home health data. This surplus varies insignificantly from the 15,237 surplus the TDOH projected on a four-year horizon (CY2020) in the original application.

This projected surplus is neither accurate nor relevant to this specialty project. First, the projection methodology is stated as a "general guideline" and it uses a simple 1.5% "need" planning factor for each county's population. A one-size-fits-all methodology is not helpful to identify the needs of such a specialized group as immune-compromised patients who require IVIG therapy. Second, the State-Plan projection methodology is seriously inaccurate. There were 39,117 actual home health agency patients served in the area in 2015, which is an evidence-based indicator of need. That utilization was 59% higher than the 24,625 patients that the 1.5% formula projects to be needed in CY2018. This alone calls into question the reliability of this projection methodology.

4. County Need Standard: The applicant should demonstrate that there is a need for home health services in each county in the proposed Service Area by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed Service Area attempted to find appropriate home health services but were not able to secure

such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

The applicant has submitted several such letters of support from area physicians who cite the need for the project, due to difficulty of finding home health providers in this service area who are able and willing to respond timely to their patients' needs with the level of service that AxelaCare proposes to provide. Physicians are not willing to provide estimates of future referrals to a prospective provider.

5. Current Service Area Utilization: The applicant should document by county: a) all existing providers of home health services within the proposed Service Area; and b) the number of patients served during the most recent 12-month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use final data provided by the JARs maintained by the Tennessee Department of Health. In each county of the proposed Service Area, the applicant should identify home health agencies that have reported serving 5 or fewer patients for each of the last three years based on final and available JAR data. If an agency in the proposed Service Area who serves few or no patients is opposing the application, that opponent agency should provide evidence as to why it does not serve a larger number of patients.

The applicant submitted three years of JAR-reported patient data for every home health agency with authorization to provide care to any of the 21 counties in the project service area. The applicant also provided the patients each agency served in CY2015 within this project's service area. That data was in Tables Six-A through Nine-C on pages 44a-44g of the application.

The applicant has identified several existing agencies that have served five or fewer patients in this service area during each of the past three years. They are shown on Supplemental Table Two, attached at the end of this response.

6. Adequate Staffing: Using TDH Licensure data, the applicant should document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and document that such personnel are available to work in the proposed Service Area. The applicant should state the percentage of qualified personnel directly employed or employed through a third party staffing agency.

AxelaCare has extensive experience in recruiting, employing, training, assessing the competencies of, and supervising and retaining skilled nursing staff to specifically manage IVIG care in the patients' homes.

AxelaCare is America's fourth largest provider of home infusion medications and services. It is a leader in research partnerships in this field of medicine. AxelaCare is accredited by the Joint Commission, and holds the Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (which supports this project by providing medications to the home health team) is accredited by URAC (originally named the Utilization Review Accreditation Program), a distinction which it earned with a 100% score on its accreditation surveys. Additional information on URAC is provided in the Attachments to the application.

AxelaCare is both a licensed pharmaceutical provider and a home health services provider. As a provider of medications, AxelaCare pharmacies prepare and ship home infusion pharmaceuticals to patients in 48 States. As a services provider in 17 States (through 33 branch offices) AxelaCare operates a full-scope program that integrates (a) the AxelaCare Pharmacy with (b) AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of those medications in patients' homes, as directed by their physicians. AxelaCare nurses and pharmacists in all 17 states are available 24/7 for patient assistance and for consultation with referring physicians -- before, during and after the patient's infusion.

Based on the above company experience and demonstrated quality, AxelaCare anticipates no problems in attracting superior staff for this project, in urban areas and healthcare centers the size of Memphis and Jackson. Implementation of this project will require development of only a small clinical staff -- between 3 and 4 skilled care nurses with documented competencies in infusion care. These will all be employed; none will be employed through a third-party staffing agency.

7. Community Linkage Plan: The applicant should provide a community linkage plan that demonstrates factors such as, but not limited to, referral arrangements with appropriate health care system providers/services (that comply with CMS patient choice protections) and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems. A new provider may submit a proposed community linkage plan.

The applicant will be a new provider of nursing services for home infusion of Immune Globulin (IG) pharmaceuticals. For this type of patient, the primary community linkages will be referring specialty physicians, because they will make referral and treatment decisions for these special-needs patients. AxelaCare will regularly call on all area specialty physician groups who serve patients with potential needs for IVIG, to keep them currently advised of AxelaCare's resources to optimize their patients' care. AxelaCare will meet monthly with all physicians who refer patients to them, to review and discuss their patient outcome data and to confer on future treatment options.

Secondary community linkages will be to area hospitals' discharge planners and medical staff. AxelaCare representatives will be in regular communication with those groups at most service area hospitals, to ensure their awareness of AxelaCare treatment options.

8. TennCare Managed Care Organizations (MCOs) and Financial Viability: Given the time frame required to obtain Medicare certification, an applicant proposing to contract with the Bureau of TennCare's MCOs should provide evidence of financial viability during the time period necessary to receive such certification. Applicants should be aware that MCOs are under no obligation to contract with home care organizations, even if Medicare certification is obtained, and that Private Duty Services are not Medicare certifiable services. Applicants who believe there is a need to serve TennCare patients should contact the TennCare MCOs in the region of the proposed Service Area and inquire whether their panels are open for home health services, as advised in the notice posted on the HSDA website, to determine whether at any given point there is a need for a provider in a particular area of the state;

letters from the TennCare MCOs should be provided to document such need. See Note 2 for additional information.

Not applicable. The applicant will not be able to serve TennCare patients because the applicant will not have a Medicare provider number, which is a condition of contracting with the MCO's.

Applicants should also provide information on projected revenue sources, including non-TennCare revenue sources.

As stated in the application, the applicant's gross revenues will be 98% from multiple commercial insurors, because the applicant will not be serving Medicare and TennCare patients. It does not seem helpful to the review process to identify the large number of commercial insurance companies who reimburse providers for IVIG care--any one of which could have a covered patient in Tennessee.

9. Proposed Charges: The applicant's proposed charges should be reasonable in comparison with those of other similar agencies in the Service Area or in adjoining service areas. The applicant should list:
a. The average charge per visit and/or episode of care by service category, if available in the JAR data.
b. The average charge per patient based upon the projected number of visits and/or episodes of care and/or hours per patient, if available in the JAR data.

Table Four on page 34 of the application provided 2015 JAR data on charges per visit and charges per hour for all area agencies who reported those. Reporting is very sketchy in the HHA Joint Annual Reports. The data is for skilled nursing only, which is the only home health service proposed in this application. However, this JAR data does not allow a meaningful comparison to AxelaCare's very different pricing structure.

AxelaCare pays its infusion nurses between $37 and $45 per hour; an average is approximately $40 per hour. However, AxelaCare projects Year One (2017) average expected nursing revenues of $240 per visit, much higher than general home health agencies who are not providing infusion care.

The only comparable specialty infusion-specific charge data identified by the applicant in publicly available sources was CN1406-018, approved in 2014 for Coram/CVS Specialty Infusion Services to do specialty home infusion care. In that document, Coram projected average charges for its "specialty infusion patient" at $290-$348 (see page 87 of Coram's CON application). In comparison, the average expected revenue per visit projected by AxelaCare for this project in 2017 is $240 for the nursing component. This is consistent with the Coram projections. The Coram 2015 Joint Annual Report provides no data on average charges. It is Coram's first such report since becoming operational in late 2015.

10. Access: In concert with the factors set forth in HSDA Rule 0720-11-.01(1) (which lists those factors concerning need on which an application may be evaluated), the HSDA may

choose to give special consideration to an applicant that is able to show that there is limited access in the proposed Service Area for groups with special medical needs such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. Pediatrics is a special medical needs population, and therefore any provider applying to provide these services should demonstrate documentation of adequately trained staff specific to this population's needs with a plan to provide ongoing best practice education. For purposes of this Standard, an applicant should document need using population, service, special needs, and/or disease incidence rates. If granted, the Certificate of Need should be restricted on condition, and thus in its licensure, to serving the special group or groups identified in the application. The restricting language should be as follows: CONDITION: Home health agency services are limited to (*identified specialty service group*); the expansion of service beyond (*identified specialty service group*) will require the filing of a new Certificate of Need application. Please see Note 3 regarding federal law prohibitions on discrimination in the provision of health care services.

The applicant will serve a relatively small specialty patient population -- those whose physicians prescribe immune globulin infusions (IVIG). It is not clear that this criterion of the State Health Plan encompasses an IVIG patient. Regardless, the applicant requests that its CON be limited to home infusion of immune globulin pharmaceuticals, consistent with the wording in this criterion.

11.Quality Control and Monitoring: The applicant should identify and document its existing or proposed plan for data reporting (including data on patient re-admission to hospitals), quality improvement, and an outcome and process monitoring system (including continuum of care and transitions of care from acute care facilities). If applicable, the applicant should provide documentation that it is, or that it intends to be, fully accredited by the Joint Commission, the Community Health Accreditation Program, Inc., the Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS.

The applicant has submitted documentation of its accreditation by the Joint Commission, including its Gold Seal award. Examples of AxelaCare's highly articulated Quality Improvement program were submitted as Attachments to the application.

12. Data Requirements: Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

The applicant so agrees, as stated on page 66 of this CON application.

Attachments:

1. Supplemental Table One: Revised Need Projection Table
2. Supplemental Table Two: Area Agencies Who Served 5 or Fewer Patients in the Service Area

SUPPLEMENTAL #1

June 23, 2016

12:14 pm

Supplemental Table One: AxelaCare West Tennessee Service Area--Three-Year Projection of Service Area Need Under State Health Plan Guidelines

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2015 Population	Use Rate	Projected 2018 Population	Projected Capacity	Projected Need	Need or (Surplus) for 2018
Tennessee	1,635	1,473	170,384	6,735,706	0.0252956409	6,962,031	176,109	104,430	(71,679)
Benton	12	11	684	16,655	0.0410687481	16,711	686	251	(436)
Carroll	13	13	1,465	28,430	0.0515300739	28,298	1,458	424	(1,034)
Chester	13	13	545	18,076	0.0301504758	18,633	562	279	(282)
Crockett	12	11	567	14,845	0.0381946783	14,982	572	225	(348)
Decatur	15	15	648	11,939	0.0542759025	12,029	653	180	(472)
Dyer	9	9	1,902	39,155	0.0485761716	39,607	1,924	594	(1,330)
Fayette	21	20	707	43,631	0.0162040751	46,608	755	699	(56)
Gibson	14	14	1,870	51,119	0.0365813103	51,934	1,900	779	(1,121)
Hardeman	15	14	920	27,285	0.0337181602	27,284	920	409	(511)
Hardin	16	15	1,101	26,479	0.0415801201	26,680	1,109	400	(709)
Haywood	15	13	649	18,477	0.0351247497	18,274	642	274	(368)
Henderson	12	12	1,209	29,101	0.0415449641	29,836	1,240	448	(792)
Henry	11	10	1,270	33,267	0.0381759702	33,771	1,289	507	(783)
Lake	7	6	357	8,230	0.0433778858	8,441	366	127	(240)
Lauderdale	14	12	907	28,529	0.0317922114	28,930	920	434	(486)
McNairy	14	14	1,138	27,019	0.0421185092	27,486	1,158	412	(745)
Madison	18	17	3,220	102,429	0.0314364096	104,799	3,295	1,572	(1,723)
Obion	10	10	1,314	31,722	0.0414223567	31,625	1,310	474	(836)
Shelby	26	26	16,269	953,899	0.0170552648	970,212	16,547	14,553	(1,994)
Tipton	21	19	1,172	66,234	0.0176948395	69,239	1,225	1,039	(187)
Weakley	15	15	1,203	35,894	0.0335153508	36,300	1,217	545	(672)
PSA TOTAL	303	289	39,117	1,612,415		1,641,679	39,747	24,625	(15,122)

*Most recent year of Joint Annual Report data for Home Health Agencies

Data is projected three years from the year the Home Health data was **finalized, not the actual year of Home Health data.

Population Data Source: The University of Tennessee Center for Business and Economic Research (UTCBER) Projection Data Files, reassembled by the Tennessee Department of Health, Division of Policy, Planning and Assessment.

Note: Population data will not match the UTCBER data exactly due to rounding.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment

April 2016

Supplemental Table 2: Agencies Serving Fewer than Five Area Residents Per Year (State Health Plan Home Health Review Criterion #5)					
State ID	Agency Name	Home County	2013 Patients	2014 Patients	2015 Patients
33103	Amedysis Home Health	Hamilton	0	0	0
79446	Baptist Trinity Home Care--Private Pay	Shelby	1	1	1
79556	Coram/CVS Specialty Infusion	Shelby	na	na	4
19544	Home Care Solutions	Davidson	0	0	0
60024	NHC HomeCare	Maury	0	2	0
41034	Saint Thomas Home Health	Hickman	0	0	1

Note: Coram/CVS was not operational until late 2015

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

12. UnitedHealth Group Earnings Report, Q1 2016

NEWS RELEASE

UNITEDHEALTH GROUP®

Investors:	Brett Manderfeld Vice President 952-936-7216	John S. Penshorn Senior Vice President 952-936-7214	Media:	Don Nathan Senior Vice President 952-936-1885	Tyler Mason Vice President 424-333-6122

(For Immediate Release)

UNITEDHEALTH GROUP REPORTS FIRST QUARTER RESULTS

- ***First Quarter Revenues of $44.5 Billion Grew 25% Year-Over-Year***
- ***UnitedHealthcare Added 2 Million More People Domestically in the Past 12 Months, Including 1.3 Million More People in the First Quarter***
- ***Optum Revenues of $19.7 Billion Grew 54% Year-Over-Year***
- ***Cash Flows from Operations were $2.3 Billion in the Quarter***
- ***First Quarter Adjusted Net Earnings of $1.81 Per Share Grew 17% Year-Over-Year***

NEW YORK, NY (April 19, 2016) – UnitedHealth Group (NYSE: UNH) today reported first quarter results, highlighted by strong execution, consistent operating performance and compelling product and service offerings driving broad-based growth across the Company.

"Our commitment and determination to constantly improve how we serve customers and consumers in health benefits and services is reflected in consistent, market-leading organic growth and strong levels of customer retention in the first quarter," said Stephen J. Hemsley, chief executive officer of UnitedHealth Group.

Based on the first quarter results and business trends, the Company now expects 2016 revenues of approximately $182 billion and adjusted net earnings in a range of $7.75 to $7.95 per share. The increase in the outlook for adjusted net earnings of $0.15 per share is due to changes in the expected income tax rate and intangible amortization. Management affirmed its outlook for strong cash flows from operations of up to $10 billion.

UNITEDHEALTH GROUP®

Quarterly Financial Performance

	Three Months Ended		
	March 31, 2016	**March 31, 2015**	**December 31, 2015**
Revenues	$44.5 billion	$35.8 billion	$43.6 billion
Earnings From Operations	$3.0 billion	$2.6 billion	$2.5 billion
Net Margin	3.6%	4.0%	2.8%

- UnitedHealth Group first quarter 2016 revenues of $44.5 billion grew 25 percent or $8.8 billion year-over-year. Growth was broad-based and reflected growing market demand for the Company's product and service offerings. UnitedHealthcare revenues grew 10 percent and Optum revenues grew 54 percent, with revenue growth of 20 percent or more at each Optum business.
- First quarter earnings from operations were $3 billion and adjusted net earnings grew 17 percent year-over-year to $1.81 per share. As expected, the first quarter net margin of 3.6 percent decreased 40 basis points year-over-year, due principally to an increased level of pharmacy care services business.
- First quarter 2016 cash flows from operations of $2.3 billion were 1.4 times net earnings.
- The consolidated medical care ratio increased 30 basis points year-over-year to 81.7 percent in the first quarter of 2016, reflecting the extra calendar day of service in the quarter. Prior year medical reserve development was $360 million, compared to $140 million in the first quarter of 2015, and first quarter 2016 medical cost trends were well-controlled and consistent with management expectations.
- The first quarter 2016 operating cost ratio of 15.2 percent decreased 110 basis points year-over-year primarily due to changes in business mix.
- The first quarter 2016 tax rate of 39.8 percent decreased 350 basis points year-over-year from 43.3 percent in first quarter 2015, due to the adoption of a new accounting standard. Under the new standard, certain corporate tax benefits related to stock-based compensation programs are recorded through the tax provision. This new standard, which added roughly $0.06 per share to net earnings due to the concentration of activity in the first quarter, is expected to have considerably less earnings impact in the remaining quarters of 2016.
- First quarter 2016 days claims payable of 51 days increased 4 days year-over-year and 1 day sequentially; days sales outstanding of 16 days increased 3 days, due to increased government receivables and business mix.
- The Company's financial position is strong, with a debt to total capital ratio of 49 percent at March 31, 2016. The Company expects this ratio to decrease during the second half of 2016 as debt levels are reduced. First quarter 2016 annualized return on equity was 19 percent, an increase of 1 percentage point year-over-year.
- UnitedHealth Group repurchased 4.2 million shares for $0.5 billion in first quarter 2016, at a weighted average price of $119 per share.

UnitedHealthcare

UnitedHealthcare provides health care benefits, serving individuals and employers ranging from sole proprietorships to large, multi-site and national and international organizations; delivers health and well-being benefits to Medicare beneficiaries and retirees; manages health care benefit programs on behalf of state Medicaid and community programs; and serves the nation's military service members, retirees and their families through the TRICARE program.

Quarterly Financial Performance

	Three Months Ended		
	March 31, 2016	**March 31, 2015**	**December 31, 2015**
Revenues	$35.9 billion	$32.6 billion	$32.8 billion
Earnings From Operations	$1.9 billion	$1.9 billion	$949 million
Operating Margin	5.2%	5.8%	2.9%

UnitedHealthcare continues to consistently grow as more customers choose its products and services, due to the combination of distinctive service, product innovation and integrated clinical and network value they offer. UnitedHealthcare has developed a balanced mix of business across the commercial, government and international markets, reflecting its deliberate strategy of diversifying and serving the breadth of needs in those markets.

- UnitedHealthcare grew organically over the past year to serve 2 million more people in the U.S. medical benefits markets, with well-diversified growth across commercial, Medicare and Medicaid offerings. First quarter growth contributed 1.3 million people to this total, helping UnitedHealthcare's first quarter revenues grow $3.3 billion or 10 percent year-over-year to nearly $36 billion.
- First quarter 2016 earnings from operations for UnitedHealthcare of $1.9 billion were roughly even with first quarter 2015, as strong growth largely offset a 60 basis point reduction in operating margins to 5.2 percent. The year-over-year margin decrease was driven by increased quarterly costs from an extra calendar day of service and public exchange performance, partially offset by reserve development.

UnitedHealthcare Employer & Individual

- UnitedHealthcare Employer & Individual grew to serve approximately 700,000 more people in the first quarter and 1 million more people year-over-year. First quarter growth was well-balanced, with growth of more than 300,000 people in risk-based and nearly 400,000 people in fee-based offerings, including increases in people served through the fee-based national account, public sector, mid-sized employer, small employer and individual segments of the market.
- First quarter revenues of $12.8 billion grew $1.4 billion or 12 percent year-over-year, driven by growth in the number of people served and price increases matching medical cost trends for risk-based products.

UnitedHealthcare Medicare & Retirement

- First quarter 2016 UnitedHealthcare Medicare & Retirement revenues of $14.1 billion grew $1.3 billion or 10 percent year-over-year, due to consistent growth in services to seniors:
  - In Medicare Advantage, UnitedHealthcare grew to serve 325,000 more seniors year-over-year, a 10 percent increase, including nearly 300,000 seniors in the first quarter.
  - Medicare Supplement products grew 7 percent to serve 270,000 more people year-over-year, including 165,000 in the first quarter.
  - UnitedHealthcare's stand-alone Medicare Part D program served 5 million people at March 31, 2016. UnitedHealthcare partially offset its planned 2016 pull-back in subsidized Part D products with an acquisition that broadened its Part D product portfolio, resulting in a net decrease of 70,000 people served in the first quarter.

UnitedHealthcare Community & State

- First quarter 2016 UnitedHealthcare Community & State revenues of $7.7 billion grew $823 million or 12 percent year-over-year due to strong overall growth and an increasing mix of higher need members.
- In the past year, UnitedHealthcare grew to serve 410,000 more people in Medicaid, an increase of 8 percent, including 145,000 more people in first quarter 2016. UnitedHealthcare continues to receive and implement new state-based awards, including serving 55,000 people as of January 1, 2016 under the New York Essential Plan and more than 200,000 people as of April 1, 2016 through the new Iowa Health Link program. UnitedHealthcare received a superior score on the re-procurement and program expansion serving Nebraska's Medicaid program in 2017.

Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, governments, life sciences companies and consumers. Using advanced data analytics and technology, Optum's people help improve overall health system performance: optimizing care quality, reducing costs and improving the consumer experience and care provider performance.

Quarterly Financial Performance

	Three Months Ended		
	March 31, 2016	**March 31, 2015**	**December 31, 2015**
Revenues	$19.7 billion	$12.8 billion	$21.9 billion
Earnings From Operations	$1.1 billion	$742 million	$1.5 billion
Operating Margin	5.6%	5.8%	6.9%

Optum's growth continues to reflect its differentiated capabilities and comprehensive solutions for stakeholders broadly across the health care system, both domestically and abroad.

- First quarter 2016 Optum revenues of $19.7 billion grew $6.9 billion or 54 percent year-over-year. Optum earnings from operations grew 49 percent or $364 million year-over-year to $1.1 billion, with solid operating margins from all business segments. Strong growth in pharmacy care services increased operating earnings and reduced Optum's overall operating margin, which decreased by 20 basis points year-over-year to 5.6 percent.
  - OptumHealth revenues of $4 billion grew $709 million or 22 percent year-over-year due to growth in its health care delivery businesses, including expansion in neighborhood care centers. OptumHealth served 79 million consumers at March 31, 2016, for growth of 8 million people or 11 percent year-over-year.
  - OptumInsight revenues grew 20 percent to $1.7 billion in the first quarter of 2016, driven by growth in technology services, care provider revenue management services and payer services. OptumInsight's revenue backlog grew to $11 billion at March 31, 2016, an increase of 21 percent year-over-year. Revenue backlog growth rates will fluctuate quarter to quarter, based on the timing of contract awards.
  - OptumRx revenues of $14.3 billion grew 72 percent year-over-year, driven by both acquisitions and organic growth. In total, OptumRx grew script fulfillment by 71 percent to 252 million adjusted scripts in the first quarter of 2016.

About UnitedHealth Group

UnitedHealth Group (NYSE: UNH) is a diversified health and well-being company dedicated to helping people live healthier lives and helping make the health system work better for everyone. UnitedHealth Group offers a broad spectrum of products and services through two distinct platforms: UnitedHealthcare, which provides health care coverage and benefits services; and Optum, which provides information and technology-enabled health services. For more information, visit UnitedHealth Group at www.unitedhealthgroup.com or follow @UnitedHealthGrp on Twitter.

Earnings Conference Call

As previously announced, UnitedHealth Group will discuss the Company's results, strategy and future outlook on a conference call with investors at 8:45 a.m. Eastern Time today. UnitedHealth Group will host a live webcast of this conference call from the Investors page of the Company's website (www.unitedhealthgroup.com). Following the call, a webcast replay will be available on the same site through May 3, 2016. The conference call replay can also be accessed by dialing 1-800-283-9429. This earnings release and the Form 8-K dated April 19, 2016 can also be accessed from the Investors page of the Company's website.

Non-GAAP Financial Measures

This news release presents information about the Company's adjusted net earnings per share, which is a non-GAAP financial measure provided as a complement to the results provided in accordance with accounting principles generally accepted in the United States of America ("GAAP"). A reconciliation of the foregoing non-GAAP financial measure to the most directly comparable GAAP financial measure is provided in the accompanying tables found at the end of this release.

Forward-Looking Statements

The statements, estimates, projections, guidance or outlook contained in this document include "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These statements are intended to take advantage of the "safe harbor" provisions of the PSLRA. Generally the words "believe," "expect," "intend," "estimate," "anticipate," "forecast," "outlook," "plan," "project," "should" and similar expressions identify forward-looking statements, which generally are not historical in nature. These statements may contain information about financial prospects, economic conditions and trends and involve risks and uncertainties. We caution that actual results could differ materially from those that management expects, depending on the outcome of certain factors.

Some factors that could cause actual results to differ materially from results discussed or implied in the forward-looking statements include: our ability to effectively estimate, price for and manage our medical costs, including the impact of any new coverage requirements; new laws or regulations, or changes in existing laws or regulations, or their enforcement or application, including increases in medical, administrative, technology or other costs or decreases in enrollment resulting from U.S., Brazilian and other jurisdictions' regulations affecting the health care industry;

assessments for insolvent payers under state guaranty fund laws; our ability to achieve improvement in CMS Star ratings and other quality scores that impact revenue; reductions in revenue or delays to cash flows received under Medicare, Medicaid and TRICARE programs, including sequestration and the effects of a prolonged U.S. government shutdown or debt ceiling constraints; changes in Medicare, including changes in payment methodology, the CMS Star ratings program or the application of risk adjustment data validation audits; our participation in federal and state health insurance exchanges which entail uncertainties associated with mix and volume of business; cyber-attacks or other privacy or data security incidents; failure to comply with privacy and data security regulations; regulatory and other risks and uncertainties of the pharmacy benefits management industry; competitive pressures, which could affect our ability to maintain or increase our market share; challenges to our public sector contract awards; our ability to execute contracts on competitive terms with physicians, hospitals and other service providers; failure to achieve targeted operating cost productivity improvements, including savings resulting from technology enhancement and administrative modernization; increases in costs and other liabilities associated with increased litigation, government investigations, audits or reviews; failure to manage successfully our strategic alliances or complete or receive anticipated benefits of acquisitions and other strategic transactions, including our acquisition of Catamaran; fluctuations in foreign currency exchange rates on our reported shareholders' equity and results of operations; downgrades in our credit ratings; adverse economic conditions, including decreases in enrollment resulting from increases in the unemployment rate and commercial attrition; the performance of our investment portfolio; impairment of the value of our goodwill and intangible assets in connection with dispositions or if estimated future results do not adequately support goodwill and intangible assets recorded for our existing businesses or the businesses that we acquire; increases in health care costs resulting from large-scale medical emergencies; failure to maintain effective and efficient information systems or if our technology products do not operate as intended; and our ability to obtain sufficient funds from our regulated subsidiaries or the debt or capital markets to fund our obligations, to maintain our debt to total capital ratio at targeted levels, to maintain our quarterly dividend payment cycle or to continue repurchasing shares of our common stock.

This list of important factors is not intended to be exhaustive. We discuss certain of these matters more fully, as well as certain risk factors that may affect our business operations, financial condition and results of operations, in our filings with the Securities and Exchange Commission, including our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. Any or all forward-looking statements we make may turn out to be wrong, and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. By their nature, forward-looking statements are not guarantees of future performance or results and are subject to risks, uncertainties and assumptions that are difficult to predict or quantify. Actual future results may vary materially from expectations expressed or implied in this document or any of our prior communications. You should not place undue reliance on forward-looking statements, which speak only as of the date they are made. We do not undertake to update or revise any forward-looking statements, except as required by applicable securities laws.

UNITEDHEALTH GROUP
Earnings Release Schedules and Supplementary Information
Quarter Ended March 31, 2016

- Condensed Consolidated Statements of Operations
- Condensed Consolidated Balance Sheets
- Condensed Consolidated Statements of Cash Flows
- Supplemental Financial Information - Businesses
- Supplemental Financial Information - Business Metrics
- Reconciliation of Non-GAAP Financial Measure

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in millions, except per share data)
(unaudited)

	Three Months Ended March 31,	
	2016	2015
Revenues		
Premiums	$ 34,811	$ 31,674
Products	6,393	1,230
Services	3,140	2,706
Investment and other income	183	146
Total revenues	44,527	35,756
Operating costs		
Medical costs	28,430	25,790
Operating costs	6,758	5,834
Cost of products sold	5,877	1,114
Depreciation and amortization	502	378
Total operating costs	41,567	33,116
Earnings from operations	2,960	2,640
Interest expense	(259)	(150)
Earnings before income taxes	2,701	2,490
Provision for income taxes	(1,074)	(1,077)
Net earnings	1,627	1,413
Earnings attributable to noncontrolling interests	(16)	—
Net earnings attributable to UnitedHealth Group common shareholders	$ 1,611	$ 1,413
Diluted earnings per share attributable to UnitedHealth Group common shareholders	$ 1.67	$ 1.46
Adjusted earnings per share attributable to UnitedHealth Group common shareholders (a)	$ 1.81	$ 1.55
Diluted weighted-average common shares outstanding	967	969

(a) See page 6 for a reconciliation of non-GAAP measure

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED BALANCE SHEETS
(in millions)
(unaudited)

	March 31, 2016	December 31, 2015 (a)
Assets		
Cash and short-term investments	$ 13,014	$ 12,911
Accounts receivable, net	7,777	6,523
Other current assets	12,954	12,205
Total current assets	33,745	31,639
Long-term investments	20,895	18,792
Other long-term assets	63,215	60,823
Total assets	$ 117,855	$ 111,254
Liabilities, redeemable noncontrolling interests and equity		
Medical costs payable	$ 15,823	$ 14,330
Commercial paper and current maturities of long-term debt	6,504	6,634
Other current liabilities	23,958	21,934
Total current liabilities	46,285	42,898
Long-term debt, less current maturities	27,218	25,331
Other long-term liabilities	7,461	7,564
Redeemable noncontrolling interests	1,824	1,736
Equity	35,067	33,725
Total liabilities, redeemable noncontrolling interests and equity	$ 117,855	$ 111,254

(a) The Company reclassified $129 of debt issuance costs related to the adoption of a new accounting standard.

UNITEDHEALTH GROUP
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in millions)
(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Operating Activities		
Net earnings	$ 1,627	$ 1,413
Noncash items:		
Depreciation and amortization	502	378
Deferred income taxes and other	151	78
Share-based compensation	157	125
Net changes in operating assets and liabilities	(119)	275
Cash flows from operating activities	2,318	2,269
Investing Activities		
Purchases of investments, net of sales and maturities	(2,073)	(545)
Purchases of property, equipment and capitalized software	(425)	(373)
Cash paid for acquisitions, net	(1,697)	(575)
Other, net	14	(32)
Cash flows used for investing activities	(4,181)	(1,525)
Financing Activities		
Common share repurchases	(500)	(896)
Dividends paid	(477)	(357)
Net change in commercial paper and long-term debt	1,599	778
Other, net	880	971
Cash flows from financing activities	1,502	496
Effect of exchange rate changes on cash and cash equivalents	34	(85)
(Decrease) increase in cash and cash equivalents	(327)	1,155
Cash and cash equivalents, beginning of period	10,923	7,495
Cash and cash equivalents, end of period	$ 10,596	$ 8,650

UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESSES
(in millions, except percentages)
(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Revenues		
UnitedHealthcare	$ 35,900	$ 32,623
Optum	19,684	12,815
Eliminations	(11,057)	(9,682)
Total consolidated revenues	$ 44,527	$ 35,756
Earnings from Operations		
UnitedHealthcare	$ 1,854	$ 1,898
Optum (a)	1,106	742
Total consolidated earnings from operations	$ 2,960	$ 2,640
Operating Margin		
UnitedHealthcare	5.2%	5.8%
Optum	5.6%	5.8%
Consolidated operating margin	6.6%	7.4%
Revenues		
UnitedHealthcare Employer & Individual	$ 12,820	$ 11,423
UnitedHealthcare Medicare & Retirement	14,065	12,781
UnitedHealthcare Community & State	7,728	6,905
UnitedHealthcare Global	1,287	1,514
OptumHealth	3,998	3,289
OptumInsight	1,667	1,390
OptumRx	14,273	8,295
Optum eliminations	(254)	(159)

(a) Earnings from operations for Optum for the three months ended March 31, 2016 and 2015 included $300 and $234 for OptumHealth; $246 and $222 for OptumInsight; and $560 and $286 for OptumRx, respectively.

UNITEDHEALTH GROUP
SUPPLEMENTAL FINANCIAL INFORMATION - BUSINESS METRICS

UNITEDHEALTHCARE CUSTOMER PROFILE
(in thousands)

People Served	March 31, 2016	March 31, 2015	December 31, 2015
Commercial risk-based	8,600	8,115	8,285
Commercial fee-based, including TRICARE	21,825	21,315	21,445
Total Commercial	30,425	29,430	29,730
Medicare Advantage	3,530	3,205	3,235
Medicaid	5,450	5,040	5,305
Medicare Supplement (Standardized)	4,200	3,930	4,035
Total Public and Senior	13,180	12,175	12,575
Total UnitedHealthcare - Domestic Medical	43,605	41,605	42,305
International	4,065	4,160	4,090
Total UnitedHealthcare - Medical	47,670	45,765	46,395
Supplemental Data			
Medicare Part D stand-alone	4,990	5,105	5,060

OPTUM PERFORMANCE METRICS

	March 31, 2016	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
OptumHealth Consumers Served (in millions)	79	71	76	77	78
OptumInsight Contract Backlog (in billions)	$ 11.0	$ 9.1	$ 9.8	$ 10.2	$ 10.4
OptumRx Quarterly Adjusted Scripts (in millions)	252	147	148	226	258

Note: UnitedHealth Group served 132 million unique individuals across all businesses at March 31, 2016, 129 million at December 31, 2015, and 101 million at March 31, 2015.

UNITEDHEALTH GROUP
RECONCILIATION OF NON-GAAP FINANCIAL MEASURE
ADJUSTED NET EARNINGS AND EARNINGS PER SHARE (a)
(in millions, except per share data)
(unaudited)

	Three Months Ended		Projected Year Ended
	March 31, 2016	March 31, 2015	December 31, 2016
GAAP net earnings	$ 1,611	$ 1,413	$6,950 to $7,200
Intangible amortization, net of tax effects	140	86	~550
Adjusted net earnings	$ 1,751	$ 1,499	$7,500 to $7,750
GAAP diluted earnings per share	$ 1.67	$ 1.46	$7.20 to $7.40
Intangible amortization, net of tax effects per share	0.14	0.09	~$0.55
Adjusted diluted earnings per share	$ 1.81	$ 1.55	$7.75 to $7.95

(a) GAAP and adjusted net earnings and earnings per share are attributable to UnitedHealth Group common shareholders.

Use of Non-GAAP Financial Measure

Adjusted earnings per share is a non-GAAP financial measure and should not be considered a substitute for or superior to a financial measure calculated in accordance with GAAP. Management believes that the use of adjusted earnings per share provides investors and management useful information about the earnings impact of acquisition-related intangible asset amortization. This non-GAAP measure does not reflect all of the expenses associated with the operations of our business as determined in accordance with GAAP. As a result, one should not consider this measure in isolation.

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

17. AxelaCare Health Solutions
Tennessee and Kansas Licensure Information

SUPPLEMENTAL #1

June 23, 2016
12:14 pm

eLicense

Kansas Board of Pharmacy
License Portal

Facility/Provider Information

Search Again

Board of Pharmacy Home | License Verification | Exam Scores

Kansas Pharmacy Board

The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

General

Name or Business:	AXELACARE HEALTH SOLUTIONS LLC	Original Date:	2/11/2015
City/State/Zip:	LENEXA, KS 66219		
Classification:	Pharmacy/Facility	On Probation:	No
L/P/R No:	2-13075 / 1.2	Discipline on File:	No
Status:	Active		

Licenses

L/P/R #	Description	Effective	Expires	Issued	Status
2-13075	Pharmacy Permit	6/6/2016	6/30/2017	2/11/2015	Active

Notes

N/A

[redacted]

SUPPLEMENTAL #1

Kansas State Board of Pharmacy June 23, 2016

12:14 pm

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Retail Pharmacy Inspection Form

Pharmacy: AXELACARE HEALTH SOLUTIONS LLC **Reg No.:** 2-13075 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Pharmacist-in-Charge: DEBORA WAGNER **License#:** 1-12933 **DEA #:** FA0905705 /

Other Pharmacist:

Type: PHARMACY **Inspector:** MELISSA MARTIN

Pharmacy Records

- [x] Prescription Files: (21 CFR 1304.04)
- [x] Prescription Content:(KSA 65-1637(b), KARs 68-20-18(c), 68-20-20(a))
- [x] Daily Print-out Dispensing Log: (KAR 68-9-1,21 CFRs 1304.04, 1306.22
- [x] OTC Sales: (KAR 68-20-22)
- [x] Invoice Record Files: (21 CFR 1304.04)
- [x] Biennial Inventory: (21 CFRs 1304.11,1304.04)
- [ ] Incident Reports: (KAR 68-7-12)
- [x] Duration of Record Keeping: (KAR 68-20-16(a))
- [x] Library: (KARs 68-7-11(b), 68-7-11(i), 68-7-11(j)(2))
- [ ] Continuous Quality Improvement Documentation: (KSA 65-1695)

Pharmacy Practice

- [x] Consumer Counseling: (KAR 68-2-20)
- [x] Technician to Pharmacist Ratio: (KSA 68-5-16)
- [x] Documentation of Technician Training: (KAR 68-5-15)

Other Miscellaneous

- [x] Prescription Labeling: (KAR 68-7-14)
- [x] Prepackaging / Repackaging Labels: (KARs 68-7-15, 68-7-16)
- [x] Necessary Equipment: (KSA 65-1642(a), KAR 68-2-12a(b))
- [x] Display of Certificates / Persons on Duty: (KSAs 65-1645(e), 65-1642(b), KAR 68-2-15)

Security

- [x] Pharmacy: (KSA 65-1637, KARs 68-1-8, 68-2-11)
- [x] Controlled Substances: (21 CFR 1301.75)

Comments: Spoke with Debora R.Ph please review CQI and Incident Report language to meet the requirements.

Date of Inspection: 1/22/2016

SUPPLEMENTAL #1

Kansas State Board of Pharmacy

June 23, 2016
12:14 pm

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC **Reg No.:** 5-31275 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Person Responsible: DEBORA WAGNER **DEA #:** FA0905705 /

Type: DISTRIBUTOR **Inspector:** MELISSA MARTIN

Record Keeping

- [x] Distribution Records: (KARs 68-14-7(f) if applicable...68-14-8)
- [ ] Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- [x] Duration of Record Keeping: (KAR 68-14-7(f)(2))

Work Area

- [x] Facilities: (KAR 68-14-7(a))
- [x] Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- [x] Security: (KAR 68-14-7(b))
- [x] Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

SUPPLEMENTAL #1

Kansas State Board of Pharmacy

June 23, 2016

12:14 pm

Landon State Office Building
800 Jackson Avenue, Suite 1414
Topeka, Kansas 66612-1231
Phone (785) 296-4056
Fax (785) 296-8420

RECEIVED
FEB 03 2016
BY:

Sam Brownback
Governor

Alexandra Blasi
Executive Secretary

AXELACARE HOLDINGS INC
15529 COLLEGE BLVD
LENEXA KS 66219

Kansas State Board of Pharmacy
Inspection Form
Distributor

Company: AXELACARE HOLDINGS INC **Reg No.:** 5-31275 **Renewal:** 6-16

Address: 15529 COLLEGE BLVD **City:** LENEXA **County:** JO **Phone:** (877) 342-9352

Person Responsible: DEBORA WAGNER **DEA #:** FA0905705 /

Type: DISTRIBUTOR **Inspector:** MELISSA MARTIN

Record Keeping

- [x] Distribution Records: (KARs 68-14-7(f) if applicable...68-14-8)
- [ ] Bi-ennial Inventory: (21 CFRs 1304.04, 1304.11)
- [x] Duration of Record Keeping: (KAR 68-14-7(f)(2))

Work Area

- [x] Facilities: (KAR 68-14-7(a))
- [x] Drug Storage / Quarantine Area: (KARs 68-14-7(a)(c)(e), 68-15-4)
- [x] Security: (KAR 68-14-7(b))
- [x] Examination of Materials: (KAR 68-14-7(d))

Comments:

Date of Inspection: 1/22/2016

RECEIVED
MAY 20 2015

NOTICE: Display this renewal with original certificate in a prominant location site

APPLICANT MAILING ADDRESS

DEBORA WAGNER
AXELACARE HEALTH SOLUTIONS LLC
15529 COLLEGE BLVD
LENEXA, KS 66219

Pharmacy
Certificate of Renewal of Permit

Original Permit #	2-13075
Pharmacy Name	AXELACARE HEALTH SOLUTIONS LLC
P.I.C. / Lic #	DEBORA WAGNER 1-12933
Address	15529 COLLEGE BLVD
City/State/Zip	LENEXA, KS 66219
Owner	AXELACARE HEALTH SOLUTIONS LLC

KANSAS STATE BOARD OF PHARMACY

Debra L. Billingsley

Executive Secretary
(785) 296-4056

2015 - 2016
Expires June 30, 2016
(This is a renewal, not an original registration)

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

SUPPLEMENTAL #1

June 23, 2016

RECEIVED pm 07 2016

STATE OF TENNESSEE
DEPARTMENT OF HEALTH
DIVISION OF HEALTH LICENSURE AND REGULATION
OFFICE OF HEALTH RELATED BOARDS
665 Mainstream Drive
Nashville, TN 37243
tennessee.gov/health

TENNESSEE BOARD OF PHARMACY
(615) 741-2718 or Fax (615) 741-2722

March 31, 2015

AxelaCare Health Solutions, LLC
15529 College Blvd.
Lenexa, KS 66219

RE: STERILE COMPOUNDING MODIFIER

To Whom It May Concern:

This letter certifies that AxelaCare Health Solutions, LLC is qualified to engage in the practices of sterile compounding under Tennessee rules and regulations. This qualification is specific to the following facility:

LICENSE TYPE:	Pharmacy
ADDRESS:	15529 College Blvd. Lenexa, KS 66219
LICENSE NUMBER:	4637

COMMENTS: Please keep a copy of this letter on file at your facility. Once the board has completed implementation of the sterile compounding modifier, an updated license will be mailed to the address on record.

Sincerely,
Ailene Lynn
Administrative Assistant II
Tennessee Board of Pharmacy

SUPPLEMENTAL #1
June 23, 2016
12:14 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:
ArcelaCare Health Solutions -- Shelby County

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 23RD day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

NOTARY PUBLIC

My commission expires July 2, 2018.

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

HF-0043

Revised 7/02

Supplemental #1 Additional Information -COPY-

Axelacare Health Solutions, LLC

CN1606-022

DSG Development Support Group

June 24, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit.

13f. The tables for "D9-Other Expenses" on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The Projected Data Chart for Nursing Only that was submitted to you on June 23 (p. 51R) had transposed digits in the Other Expenses entry for Year Two. That number should have been $19,783 rather than $19,873. Revised page 51R2 is attached to this letter, correcting the transposition. Also attached is revised page 55R2, whose Table Eleven-A needed to be corrected as a result of changing the Projected Data Chart for Nursing.

17. Section C, Contribution to Orderly Development, Item 7d
a. If possible, please provide the latest copy of the Axelacare's Specialty Pharmacy Program Inc.'s licensure survey and approved plans of correction.

The Tennessee Board of Pharmacy does not inspect the Alexa facility. Only Kansas licensure and inspection are required. That is the reason the Board of Pharmacy has established a non-resident pharmacy license.

4219 Hillsboro Road, Suite 203
Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

18. Proof of Publication

Please provide copies of the publication of intent of the required 4 newspapers of general circulation in the proposed service area as listed in the letter of intent. Please submit a copy of the full page of the newspaper in which the notice of intent appeared with the mast and dateline intact or submit a publication affidavit which is supplied by the newspaper as proof of the publication of the letter of intent that covers the 21 county proposed service area. Please insure the correct complete copy is paired with each appropriate affidavit.

The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn
Consultant

SUPPLEMENTAL #1
June 24, 2016
12:12 pm

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AXELACARE -- WEST TN

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

John L Wellborn
Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 24th day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

Jan M. Danforth
NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

ADDITIONAL INFORMATION Supplemental #1 -COPY-

AXELAcARE HEALTH SOLUTIONS

CN1606-022

DSG Development Support Group

June 27, 2016

Phillip M. Earhart, HSD Examiner
Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: CON Application CN1606-022
AxelaCare Health Solutions, LLC

Dear Mr. Earhart:

This letter responds to your recent request for additional information on this application. The items below are numbered to correspond to your questions. They are provided in triplicate, with affidavit. This replaces the materials delivered on June 24.

13f. The tables for "D9-Other Expenses" on page 54 are noted. However, the categories do not match the categories as listed in the three submitted Projected Data Charts. Please revise.

The Projected Data Chart for Nursing Only that was submitted to you on June 23 (p. 51R) had transposed digits in the Other Expenses entry for Year Two. That number should have been $10,783 rather than $10,873. Revised page 51R2 is attached to this letter, correcting the transposition. Also attached is revised page 55R2, whose Table Eleven-A needed to be corrected as a result of changing the Projected Data Chart for Nursing.

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Nashville, TN 37215
jwdsg@comcast.net
Tel 615.665.2022
Fax 615.665.2042

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The newspaper affidavits and/or tearsheets for proof of publication are being submitted to you by Brant Phillips' staff at Bass Berry & Sims. He is the CON legal counsel for this applicant and can serve as joint contact person.

Thank you for your assistance. We hope this provides the information needed to accept the application into the next review cycle. If more is needed please email me at jwdsg@comcast.net or telephone me at 615-665-2022, so that we can respond in time to be deemed complete.

Respectfully,

John Wellborn

John Wellborn
Consultant

AFFIDAVIT

STATE OF TENNESSEE

COUNTY OF DAVIDSON

NAME OF FACILITY:

AXECARE – W.TN

I, JOHN WELLBORN, after first being duly sworn, state under oath that I am the lawful agent of the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete to the best of my knowledge.

JAN M. DANFORTH
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
My Commission Expires July 2, 2018

John L Wellborn

Signature/Title
CONSULTANT

Sworn to and subscribed before me, a Notary Public, this the 27th day of June, 2016, witness my hand at office in the County of DAVIDSON, State of Tennessee.

NOTARY PUBLIC

My commission expires July 2, 2018.

HF-0043

Revised 7/02

The Commercial Appeal
Affidavit of Publication

STATE OF TENNESSEE
COUNTY OF SHELBY

Personally appeared before me, Patrick Maddox, a Notary Public, Marianne Sheridan, of MEMPHIS PUBLISHING COMPANY, a corporation, publishers of The Commercial Appeal, morning and Sunday paper, published in Memphis, Tennessee, who makes oath in due form of law, that she is Legal Clerk of the said Memphis Publishing Company, and that the accompanying and hereto attached advertisement was published in the following editions of The Commercial Appeal, to-wit:

June 10, 2016

Marianne Sheridan

Subscribed and sworn to before me this 10th day of June, 2016.

Notary Public

My commission expires January 20, 2020.

PATRICK MADDOX
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF SHELBY

brances as well as any priority created by a fixture filing; and to any matter that an accurate survey of the premises might disclose. In addition, the following parties may claim an interest in the above-referenced property:
HELEN DAWSON
The sale held pursuant to this Notice may be rescinded at the Successor Trustee's option at any time. The right is reserved to adjourn the day of the sale to another day, time, and place certain without further publication, upon announcement at the time and place for the sale set forth above. W&A No. 314656
DATED May 25, 2016
WILSON & ASSOCIATES P.L.L.C.,
Successor-Trustee
1521 Merrill Drive, Suite D-220
Little Rock, Arkansas 72211
(501) 219-9388
W&A No.-314656
CA3T-
6/10/16
6/17/16
6/24/16
FOR SALE INFORMATION, VISIT WWW.MYFIR.COM and WWW.REALTYTRAC.COM

SUBSTITUTE TRUSTEE'S SALE

Sale at public auction will be on **July 29, 2016 on or about 12:00PM local time,** at the Southwest Corner, Adams Avenue Entrance of the Shelby County Courthouse, Memphis, Tennessee, conducted by the Substitute Trustee as identified and set forth herein below, pursuant to Deed of Trust executed by TERRI K. ERBY, to HOME SURETY TITLE AND ESCROW, LLC, Trustee, on December 29, 2005, as Instrument No. 06005614 in the real property records of Shelby County Register's Office, Tennessee.

USA, N.A., AS TRUSTEE ON BEHALF OF ACE SECURITIES CORP. HOME EQUITY LOAN TRUST AND FOR THE REGISTERED HOLDERS OF ACE SECURITIES CORP. HOME EQUITY LOAN TRUST, SERIES 2006-ASAP2, ASSET BACKED PASS-THROUGH CERTIFICATES
The following real estate located in Shelby County, Tennessee, will be sold to the highest call bidder subject to all unpaid taxes, prior liens and encumbrances of record:
LOT 77, PHASE 2, STONEBRIAR P.D., PART OF AREA 1 & AREA 4, AS SHOWN ON PLAT OF RECORD IN PLAT BOOK 219, PAGE 53, IN THE REGISTER`S OFFICE OF SHELBY COUNTY, TENNESSEE, TO WHICH PLAT REFERENCE IS HEREBY MADE FOR A MORE PARTICULAR DESCRIPTION OF SAID PROPERTY.
BEING THE SAME PROPERTY CONVEYED HEREIN BY WARRANTY DEED RECORDED SIMULTANEOUSLY HEREWITH IN THE REGISTER`S OFFICE OF SHELBY COUNTY, TENNESSEE.
Tax ID: D0255F0G000320
Current Owner(s) of Property: TERRI K. ERBY
The street address of the above described property is believed to be 7661 Brrokbriar Cove, Memphis, TN 38125, but such address is not part of the legal description of the property sold herein and in the event of any discrepancy, the legal description referenced herein shall control.
SALE IS SUBJECT TO OCCUPANT(S) RIGHTS IN POSSESSION.
THE RIGHT IS RESERVED TO ADJOURN THE DAY OF THE SALE TO ANOTHER DAY, TIME AND PLACE CERTAIN WITHOUT FURTHER PUBLICATION, UPON ANNOUNCEMENT AT THE TIME AND PLACE FOR THE SALE SET FORTH ABOVE. THE

TRUSTEE/SUBSTITUTE RESERVES THE RESCIND THE SALE. SALE IS SET ASIDE REASON, THE PURCH THE SALE SHALL BE ONLY TO A RETURN DEPOSIT PAID. THE P ER SHALL HAVE NO RECOURSE AGAINS GRANTOR, THE GRAN THE TRUSTEE.
OTHER INTERESTED EAGLE MORTGAGE & CORPORATION, TEN CORPORATION - JUNI AND STONEBRIAR HOI ERS ASSOCIATION, INC
THIS IS AN ATTEMPT LECT A DEBT AND ANY MATION OBTAINED V USED FOR THAT PURPO
If applicable, the notice ments of T.C.A. 35-5-1 been met.
All right of equity of r tion, statutory and oth and homestead are ex waived in said Deed o and the title is believe good, but the undersigr sell and convey only as tute Trustee.
If the U.S. Department o sury/IRS, the State o nessee Department of nue, or the State of T see Department of La Workforce Developme listed as Interested Par the advertisement, the Notice of this foreclos being given to them ar Sale will be subject t applicable governmenta ties' right to redeem the erty as required by 26 7425 and T.C.A. §67-1-143
This property is being sold the express reservation the sale is subject to conf tion by the lender or tru This sale may be resci at any time. If the sale i aside for any reason, the chaser at the sale sha entitled only to a return o deposit paid. The Purch shall have no further reco against the Mortgagor, Mortgagee or the Mortgag attorney.
MWZM File No. 15-003983-
JASON S. MANGRUM, JOHN R. ROAN, or JERRY A. BRIDENBAUGH,
Substitute Trustee(s)
PREMIER BUILDING, SUITE 4
5217 MARYLAND WAY
BRENTWOOD, TENNESSEE 37
PHONE: (615) 238-3630
EMAIL: TNSALES@MWZML COM

SUBSTITUTE TRUSTEE'S SA

Sale at public auction will be June 28, 2016 at 1:00PM lo time, at the east door, L derdale County Courthou 100 Court Square, Ripley, T nessee, pursuant to Deed Trust executed by Michael and Leavata Lee, to Willi Dan Douglas, Jr., Trustee, July 24, 2002 at Record Bo 472, Page 219, Instrument N 121688; all of record in t Lauderdale County Registe Office.
Party entitled to enforce sec rity interest: Federal Nation Mortgage Association ("Fa nie Mae"), a corporation org nized and existing under th laws of the United States America, its successors ar assigns
The following real estate loca ed in Lauderdale Count Tennessee, will be sold to th highest call bidder subject t all unpaid taxes, prior lien and encumbrances of record:
Lying and being in the 2nd Civ District of Lauderdale County

Legal Notices

Legal Notices

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street, Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development

The Paris Post-Intelligencer

PROOF OF PUBLICATION

State of Tennessee --- Henry County:

This day personally before me the undersigned came **Michael B. Williams**, Proprietor of **The Paris Post-Intelligencer**, a daily newspaper published in Paris, Tennessee, who makes oath in due form of law that the advertisement for Intent to Apply, a copy of which has been provided, was published in said paper 6-10-16 and the printer's fee for same is $ 170.56.

Michael B Williams

Sworn and subscribed to me this 23 day of June 2016.

DANIEL WILLIAMS STATE OF TENNESSEE NOTARY PUBLIC HENRY COUNTY

Notary

My commission expires: August 22, 2017

CLASSIFIEDS

208 E. Wood Street Paris, TN 38242 (731) 642-1162 classifieds@parispi.net | www.parispi.net

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98 Want To Buy

02 | PUBLIC NOTICE

NOTICE TO CREDITORS
Estate of : Dorothy M. Newcomb
Henry County, Tennessee

Notice is hereby given that on May 26, 2016 letters testamentary (or of administration as the case may be) in respect of the estate of Dorothy M. Newcomb who died August 30, 2015 were issued to the undersigned by the Clerk and Master of Henry County, Tennessee. All persons, resident and non-resident, having claims, matured or unmatured, against the estate are required to file the same with the Clerk of the above-named Court on or before the earlier of the dates prescribed in (1) or (2) otherwise their claims will be forever barred:
(1) (A) Four (4) months from the date of the first publication (or posting, as the case may be) of this notice if the creditor received an actual copy of this notice to creditors at least sixty (60) days before date that is four (4) months from the date of the first publication (or posting); or
(B) Sixty (60) days from the date the creditor received an actual copy of the notice to creditors, if the creditor received the copy of the notice less than sixty (60) days prior to the date that is four (4) months from the date of the first publication (or posting) as described in (1)(A); or
(2) Twelve (12) months from the decedent's date of death. All persons indebted to the above Estate must come forward and make proper settlement with the undersigned at once.
This 26th day of May, 2016.

Robin Lee Bell
Executrix

Attorney:
Steve Greer
ESTATE OF:
Dorothy M. Newcomb
Mary G. Burns
Clerk and Master

SUBSTITUTE TRUSTEE'S SALE

Sale at public auction will be on July 14, 2016 at 11:00AM local time, at the north door, Henry County Courthouse, 100 Washington Street, Paris, Tennessee, pursuant to Deed of Trust executed by Ricky A. Hargrove and Tara Hargrove, to Kathy J. Winstead, Trustee, on June 6, 2002 at Record Book 77, Page 660, Instrument No. 28235; all of record in the Henry County Register's Office.
Party entitled to enforce security interest: Federal National Mortgage Association ("Fannie Mae"), a corporation organized and existing under the laws of the United States of America, its successors and assigns.
The following real estate located in Henry County, Tennessee, will be sold to the highest call bidder subject to all unpaid taxes, prior liens and encumbrances of record:
That certain real estate located in the Third Civil District of Henry County, Tennessee, known as Assessor's Map 107, Group -, Parcel 68.01 and being more particularly described as follows:
BEGINNING IN THE SOUTH MARGIN OF WHISPERING PINES ROAD, THE NORTHWEST CORNER OF THIS DESCRIBED REAL ESTATE; THENCE WITH WHISPERING PINES ROAD, SOUTH 72 DEG. 14 MIN. 06 SEC. EAST 100.00 TO AN IRON PIN FOUND; THENCE SOUTH 02 DEG. 50 MIN. 58 SEC. WEST 322.13 FEET TO AN IRON PIN FOUND, THE SOUTHEAST CORNER OF THIS DESCRIBED REAL ESTATE; THENCE NORTH 86 DEG. 20 MIN. 13 SEC. EAST 85.00 FEET TO AN IRON PIN SET; THENCE WITH CROUCH'S WEST BOUNDARY LINE, NORTH 00 DEG. 30 MIN. 34 SEC. WEST 207.86 FEET TO AN IRON PIN SET; THENCE CONTINUING WITH CROUCH'S WEST BOUNDARY LINE, NORTH 02 DEG. 50 MIN. 58 SEC. EAST 150.00 FEET TO THE POINT OF BEGINNING, CONTAINING 0.72 ACRES, according to the survey of Larry I. Smith, Tenn. Reg. No. 824, dated March 8, 1984.
Subject to that certain Water Easement of record in Deed Book 74, page 15, in the Register's Office of Henry County, Tennessee.
Subject to that certain Right of Way Easement between Herman Bruhn and the City of Paris, dated May 20, 1940, of record in Deed Book 43, at pages 62-63, in the Register's Office of Henry County, Tennessee.
This being the same real estate conveyed to Ricky A. Hargrove and wife, Tara Hargrove by deed of James R. Crouch and wife, Lyda Gail Crouch, dated October 3, 1997 and of record in Deed Book 254, page 744, in the Register's Office of Henry County, Tennessee. Also see the deed of correction, correcting the description, of record in Deed Book 255, page 387, in the Register's Office of Henry County, Tennessee.
Parcel Number: 107 068.01
Current Owner(s) of Property: Ricky A. Hargrove and wife, Tara Hargrove
Other interested parties: LVNV Funding, LLC, as assignee of "Citifinancial, Inc." c/o Shon Leverett, Attorney
Street Address: 192 Whispering Pines Road, Paris, Tennessee 38242
Any property address provided is not part of the legal description of the property sold herein and in the event of any discrepancy, the legal description referenced herein shall control.
All right of equity of redemption, statutory and otherwise, and homestead are expressly waived in said Deed of Trust, and the title is believed to be good, but the undersigned will sell and convey only as Substitute Trustee.
If you purchase a property at the foreclosure sale, the entire purchase price is due and payable at the conclusion of the auction in the form of a certified/bank check made payable to or endorsed to Shapiro & Ingle, LLP. No personal checks will be accepted. To this end, you must bring sufficient funds to outbid the lender and any other bidders. Insufficient funds will not be accepted. Amounts received in excess of the winning bid will be refunded to the successful purchaser at the time the foreclosure deed is delivered.
This property is being sold with the express reservation that the sale is subject to confirmation by the lender or trustee. This sale may be rescinded at any time.

Shapiro & Ingle, LLP,
a Tennessee limited liability partnership
Substitute Trustee

www.auction.com
File No. 14-057718

SUBSTITUTE TRUSTEE'S SALE

Sale at public auction will be on July 14, 2016 at 11:00AM local time, at the north door, Henry County Courthouse, 100 Washington Street, Paris, Tennessee, pursuant to Deed of Trust executed by Diane Williamson, to Mid-South Title Corp, Trustee, on December 5, 2007 at Book 251, Page 227; all of record in the Henry County Register's Office.
Party entitled to enforce security interest: Nationstar Mortgage LLC, its successors and assigns.
The following real estate located in Henry County, Tennessee, will be sold to the highest call bidder subject to all unpaid taxes, prior liens and encumbrances of record:
TRACT NO. 1: LAND LOCATED APPROXIMATELY THREE MILES NORTHWEST OF PARIS AND ON THE NORTH SIDE OF TENNESSEE STATE HIGHWAY NO. 69; BEGINNING AT STEVE MOHON'S SOUTHWEST CORNER, THE SOUTHEAST CORNER OF THE HEREIN DESCRIBED TRACT, AN IRON PIN AND STEEL POST 33 FEET FROM THE CENTER OF TENNESSEE STATE HIGHWAY NO. 69; THENCE FROM THE POINT OF BEGINNING WITH THE NORTH RIGHT -OF WAY OF HIGHWAY 69, 33 FEET FROM ITS CENTERLINE NORTH 52 DEGREES 48 MINUTES WEST 182.7 FEET TO A STEEL POST 33 FEET FROM THE CENTER OF THE HIGHWAY AND 1.8 FEET WEST OF THE CENTER OF A POWER POLE; THENCE SEVERING THE LAND OF W.A. MOHON, NORTH 5 DEGREES 20 MINUTES EAST 188.7 FEET TO A STEEL POST; THENCE SOUTH 88 DEGREES 47 MINUTES EAST 307.2 FEET TO A STEEL POST; THENCE SOUTH 15 DEGREES 12 MINUTES EAST 102.5 FEET TO A STEEL POST IN STEVE MOHON'S WEST LINE SOUTH 47 DEGREES 00 MINUTES WEST, 283.0 FEET TO THE POINT OF BEGINNING CONTAINING 1.67 ACRES ACCORDING TO SURVEY DATED November 29, 1985 OF AARON STEELE, RLS, TN REG. NO. 460,205 OGBURN STREET, PARIS, TENNESSEE 38242.
TRACT NO. 2: A 3.656 ACRE TRACT OF LAND, AS SURVEYED BY THE FIRM OF TRINITY ENGINEERING, INC. ON November 201994, LOCATED APPROXIMATELY 2.3 MILES NORTH OF THE CITY OF PARIS, IN THE FIRST CIVIL DISTRICT OF HENRY COUNTY, TENNESSEE AND KNOWN AS A MINOR SUBDIVISION PLAT OF W.A. MOHON, JR. PROPERTY AS RECORDED IN PLAT CABINET C, SLIDE 7, IN THE REGISTER'S OFFICE OF HENRY COUNTY, TENNESSEE AND BEING MORE PARTICULARLY DESCRIBED AS FOLLOWS: COMMENCING AT A CONCRETE MONUMENT (FOUND) 32' NORTH OF THE TN. HWY. 69, SAID MONUMENT BEING THE SOUTHWEST CORNER OF THE RANDY MOHON PROPERTY (DB 198, PG 360) AND THE SOUTHEAST CORNER OF THE LEV ADA MOHON PROPERTY (DB 212, PG 713); THENCE NORTH 10 DEGREES 41 MINUTES 18" EAST FOR A DISTANCE OF 188.70 FEET TO A CONCRETE MONUMENT (FOUND) AT THE NORTHWEST CORNER OF RANDY MOHON SAID MONUMENT BEING THE TRUE POINT OF BEGINNING; THENCE NORTH 10 DEGREES 41 MINUTES 18 SECONDS EAST FOR A DISTANCE OF 326.96 FEET WITH THE EAST LINE OF LEV ADA MOHON TO A 1 1/2" ANGLE IRON (FOUND) IN THE SOUTH LINE OF THE LUDSON PALMER PROPERTY (DB 9, PG 545); THENCE SOUTH 88 DEGREES 57 MINUTES 53 SECONDS EAST FOR A DISTANCE OF 404.34 FEET WITH THE ABOUT LINE OF PALMER TO A 3/4" IRON PIPE (FOUND) AT THE NORTHWEST CORNER OF THE W.A. MOHON, JR. PROPERTY (DB 215, PG 738); THENCE SOUTH 02 DEGREES 50 MINUTES 29 SECONDS WEST FOR A DISTANCE OF 455.63 FEET WITH THE WEST LINE OF W.A. MOHON, JR. TO A #4 REBAR (FOUND) AT THE NORTHWEST CORNER OF THE MOHON INTERNATIONAL, INC. PROPERTY (DB 234, PG 128); THENCE NORTH 85 DEGREES 56 MINUTES 13 SECONDS WEST FOR A DISTANCE OF 114.10 FEET WITH THE NORTH LINE OF RANDY MOHON TO A POINT; THENCE NORTH 13 DEGREES 05 MINUTES 07 SECONDS WEST FOR A DISTANCE OF 102.50 FEET TO A POINT; THENCE NORTH 83 DEGREES 25 MINUTES 42 SECONDS WEST FOR A DISTANCE OF 307.20 FEET CONTINUING WITH THE NORTH LINE OF RANDY MOHON TO THE POINT OF BEGINNING.
TRACT NO. 3: BEGINNING AT AN IRON PIN AND STEEL POST LOCATED IN STEVE W. MOHON'S SOUTHWEST CORNER AND 33 FEET FROM THE CENTER OF TENNESSEE HIGHWAY NO. 69; THENCE NORTH 47 DEGREES 00 MINUTES EAST 283.0 FEET TO A STEEL POST, THE NORTHWEST CORNER OF THIS TRACT, THENCE NORTH 87 DEGREES 30 MINUTES EAST 114.1 FEET TO AN EIGHT INCH SASSAFRAS TREE, THENCE SOUTH 5 DEGREES 00 MINUTES EAST 101.6 FEET TO A POINT IN MOHON'S EAST LINE, THE WEST LINE OF GERALD WEBB; THENCE SOUTH 80 DEGREES 15 MINUTES WEST 202.0 FEET; THENCE SOUTH 30 DEGREES 00 MINUTES WEST, 129.0 FEET TO A POLE IN THE NORTH MARGIN OF TENNESSEE HIGHWAY NO. 69; THENCE, ALONG THE NORTH MARGIN OF THE HIGHWAY, NORTH 52 DEGREES 53 MINUTES WEST 82.0 FEET TO THE POINT OF BEGINNING CONTAINING .74 ACRES MORE OR LESS.
EXCLUDING THEREFROM THAT PORTION OF SAID PREMISES ALL PREVIOUSLY RE-CONVEYED BY DEED OF RECORD IN DEED BOOK 186, PAGE 559. SUBJECT TO ANY ADDITIONAL ROAD AND UTILITY EASEMENT THAT MAY EXIST ALONG STATE HIGHWAY 69.
Parcel Number: 085 84.07
Current Owner(s) of Property: Diane Williamson
Street Address: 1910 Hwy 69 North, Paris, Tennessee 38242
Any property address provided is not part of the legal description of the property sold herein and in the event of any discrepancy, the legal description referenced herein shall control.
All right of equity of redemption, statutory and otherwise, and homestead are expressly waived in said Deed of Trust, and the title is believed to be good, but the undersigned will sell and convey only as Substitute Trustee.
If you purchase a property at the foreclosure sale, the entire purchase price is due and payable at the conclusion of the auction in the form of a certified/bank check made payable to or endorsed to Shapiro & Ingle, LLP. No personal checks will be accepted. To this end, you must bring sufficient funds to outbid the lender and any other bidders. Insufficient funds will not be accepted. Amounts received in excess of the winning bid will be refunded to the successful purchaser at the time the foreclosure deed is delivered.
This property is being sold with the express reservation that the sale is subject to confirmation by the lender or trustee. This sale may be rescinded at any time.

Shapiro & Ingle, LLP,
a Tennessee limited liability partnership
Substitute Trustee

www.auction.com
File No. 16-106298

TEMPORARY AGRICULTURAL LABORERS
08-01-16 to 12-01-16
LEON ROGERS, BUCHANAN, TN
4 OPENINGS

Seek 4 farm workers for tobacco crops. With 3 months experience. Temporary 08-01-16 to 12-01-16. $10.83/hr. 75% of the total contract hours guaranteed. Free work tools, supplies & equip. provided free. Free housing to workers who can't return to their permanent residence at the end of each work day. Transportation & subsistence expenses provided to non-resident workers at 50% of the contract completion. Random drug test (after hire) at employer's cost. Contact TN Dept. of Labor & Workforce, 615-741-5671, or reach out to your nearest employment office. JO # [illegible]

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton & Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care Facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

SOUTH PARIS WATER CO-OP
WATER RATES ARE RAISING
DUE TO NEEDED MAINTENANCE ON AGING INFRASTRUCTURE

Min. Bill $29.80 + tax includes first 2,000 gallons of water; $6.64 per thousand after.
Effective 7/1/2016

SERVICE DIRECTORY

FUNERAL HOME
McEvoy Funeral Home - 642-1441

HEAT & AIR CONDITIONING
Bart Sturdivant Service - 644-0900

HOME MAINTENANCE
Paint Plus Flooring, 731-642-1900

PLUMBING
Jeff's Plumbing - 644-1053 or 707-1260
Robbie to the Rescue Plumbing Services
642-4872 or 336-1340

REAL ESTATE
Moody Realty Company, Realtors
642-5093

TRANSMISSIONS
Terry's Automatic Transmissions
642-7051

To advertise your business in this Service Directory, call 642-1162

CONSTRUCTION CREW
PARIS SPECIAL SCHOOL DISTRICT
Accepting Applications for the following positions:

CONSTRUCTION SUPERINTENDENT
Applicant must have a minimum seven (7) years experience serving as the lead Superintendent on School Projects; with a value of $8 million dollars or more. Familiarity working directly for TN School Systems under a Construction Manager - Advisor Format is necessary.

CARPENTERS/ CARPENTERS HELPERS/LABORERS
Experience w/Commercial Concrete Work helpful.
Project will last approximately (2) years.
Applicants must pass TBI Background Check and Drug Test prior to Employment.

Contact **Henson Construction Services** at **664-5858** *for PSSD Applications*

04 | NOTICE

GREYSTONE HOTEL In Paris, Ballroom & Dining Room available for weddings, receptions, reunions, showers, club meetings or other events. Tables & chairs available, as well as catering. Call (731)644-5113.

KY LAKE Beekeepers will have a field day June 11th, 9:30am at Dottie & Baker Kendall's, Elkhorn Nobles Rd. Bring a chair, potluck. Some extra protection available. Call (731)363-3523.

TO WHOM it may concern, for towing and storage: A 1994 Chevy, Vin# 1GDHP32Y5R3500553 will be sold on July 15th, 2016. Brockwell Towing & Recovery, (731)707-2627.

08 | FOUND

2 Dogs black/white male, and brown w/ black stripes female. Call (731)336-0642.

12 | HELP WANTED

DRIVERS!
No experience? No problem! 14 day, local training in Jackson, TN to earn great pay, benefits, job security. Placement assistance & student tuition loans available. Call 1-800-423-8820 or go to www.drive-train.org for training opportunity with DRIVE-TRAIN, 119 E.L. Morgan Drive in Jackson.

PART-TIME HOUSEKEEPING
Position available. 5 days, morning shift. Resume only at Super 8, 1309 E. Wood St., Paris.

NOTICE OF BEER LICENSE APPLICATION

Owner or Manager:
DOUGLAS HUGH KEETON

Name of Business:
SLIDE & RIDE TAVERN, LLC

Address of Business:
11180 HWY. 79N, SPRINGVILLE, TN 38256

Former Business:
MATT'S PUB

Applicant has applied for a Beer License to sell Beer at the above address: On and Off Premises Consumption.
The **COUNTY BEER BOARD** will meet **JUNE 23, 2016, at 7:00 p.m.** at the **Courthouse** to hear arguments for or against the granting of this license.

ACCEPTING APPLICATIONS at the Paris Sonic between 1pm & 2pm. Absolutely no phone calls accepted. EOE

ACCEPTING APPLICATIONS for Pre-School Teacher, experience required. Call for information. (731)642-5437.

DRIVERS-CO & O/Op's. Earn Great Money Running Dedicated! Great Benefits. Home Weekly. Monthly Bonuses. Drive Newer Equipment! 855-582-2265

EXPERIENCED COMMERCIAL mowing help wanted. DL required, references required. Call between 8am-5pm. No Sunday calls. (731)782-3524

EXPERIENCED OTR Flatbed truck driver. Must have good driving record. Some loads are OD. Late model tractors & trailers. Please call (731)336-0339, (731)593-0852.

FULL-TIME LICENSED Cosmetologist or Barber needed. Must apply in person, Fantastic Sams, 1023 Mineral Wells Ave, Ste B, Paris, TN.

HIRING CONSTRUCTION laborer. (731)363-6097.

J. R. HAYES Construction Co. has openings for a dump truck driver & heavy equipment operator and for a plant operator at their gravel pit. Driver applicants should have two years relevant experience, a class B CDL, a current health card, and a clean MVR. Operators should have two years relevant experience and a driver's license. Plant operators should have experience in maintenance, welding and electrical experience preferred. All applicants should apply in person at the main office, 2525 Hwy. 79S, Paris. No phone calls. 401k and insurance available. A Drug-Free workplace, and an Equal Opportunity Employer, women and minorities are encouraged to apply.

LOCAL BANK Now Hiring – Part-Time Teller Positions available. Candidate must have the ability to provide service to customers by processing financial transactions promptly, correctly and efficiently. Maintain responsibility for cash drawer and follow proper balancing procedures. Banking experience is preferred but not required, excellent communication and customer service skills are essential. Employer is an Equal Opportunity Employer. Please send resume by e-mail to: myparisbank@gmail.com or by mail to: PO Box 310-205, Paris, TN 38242

NOW ACCEPTING resumes for busy fast food restaurant management. Pay based on experience, serve-safe certification required, mail resume to, P.O. Box 310-154, Paris, TN. 38242. EOE

NOW HIRING Clerical Staff at MMC, a family practice medical facility committed to quality care. Shifts are 8am-5pm or 10am-7pm, Monday- Friday, with some Saturday work required. Must Have: High School Diploma/GED, Competent Computer Skills & Clean Drug Screen. Mail or bring resume to 205 Hospital Drive, McKenzie 38201.

NOW HIRING LPNs, CNAs & MAs at MMC, a family practice medical facility committed to quality care. Shifts are 8am-5pm or 10am-7pm Monday-Friday, with some Saturday work required. Must Have: High School Diploma/GED, Competent Computer Skills & Clean Drug Screen. Mail or bring resume to 205 Hospital Drive, McKenzie 38201.

NOW HIRING Tom's Pizza & Steak House Experienced Cooks and all positions still available. Immediate openings. Apply in person, 2501 East Wood St. Paris, TN

OPTOMETRIC TECH needed, send resume to: P.O. Box 310-125, Paris, TN 38242.

PAINTING CONTRACTOR is recruiting professional painters with 2 years experience, painters trainee program positions are also available. Call (270)753-6895 to apply and leave voice message. Benefit program includes 401K and vacations. No walk in applicants accepted. EOE

18 | JOB POSITION WANTED

CRITTER SITTER Pet-sitting/Housesitting, Bonded, Insured, excellent references. 15 years experience as Humane Society Officer. Carol Douglas, (731)642-6212, (731)363-6751, crittersitter1956@charter.net

LOOKING FOR work, labor or otherwise in Paris, have strong hands and back and willing to work: Dan, (731)227-0389.

22 | BUSINESS SERVICE

HOUSE WASHING
Mold & mildew removal! Pressure washing concrete, brick, vinyl siding, decks, free estimates, licensed & insured. Greg Collums, Volunteer Pressure Washing, (731)642-2671, (731)697-1972.

TOP SOIL
LEWY'S SOD & Landscaping. Sod, landscaping, mulching, lawn mowing, fill sand, gravel. Free estimates. Licensed and insured. (731)225-1030.

ELLIOTT'S PAINTING PLUS
Licensed/Insured. Painting (interior/exterior), pressure washing, metal roofs, decks, carpentry, vinyl siding, etc. Free estimates. (731)336-3604, (731)363-4556.

BAIL BOND
Pot O' Gold, (731)644-9113, 24 hour service.

SERVALL LLC HOME REPAIRS
Floor Support, Support Beams, Floor Joist, Interior French Drains, Sump Pumps, ground Cover, Fungi Treatments, Dryer Vents, Access Doors, Dehumidifiers, Termite & Pest Control. Free Estimates. Credit cards accepted. (731)642-4461.

AFFIDAVIT OF PUBLICATION

0001341971
Newspaper Jackson Sun

State of Tennessee

Account Number NAS-523833
Advertiser BASS, BERRY, & SIMS

BASS, BERRY, & SIMS
BASS BERRY
150 3RD AVE S STE 2800
NASHVILLE, TN 37201

TEAR SHEET ATTACHED

Jackie Cooper Sales Assistant for the above mentioned newspaper, hereby certify that the attached advertisement appeared in said newspaper on the following dates:

✓

06/10/16

Jackie Cooper

Subscribed and sworn to before me this 14 day of June 2016

Angela Murray
Notary Public

ANGELA MURRAY
STATE OF TENNESSEE NOTARY PUBLIC
DAVIDSON COUNTY
MY COMMISSION EXPIRES 1-6-2020

0001341971NOTIFICATIONOFINTENTTOAPPLYFORACE
Re: Cert of Need

classifieds

wheels « homes « merch « announce « jobs

Whats Hot Announce

messages & notices...

Adoptions

ADOPTION: Loving couple promises your baby a secure, happy home Denise & Nick, [illegible]

Announcements

ABC Server Permit Classes & Certification Test ★ ★ ★ 731-217-9022 ★ ★ ★

Found

Intact male blue/gray pit bull, less than 1 year old, found near the CVS on N Highland. Very sweet and very hyper. (731)425-4216

Lost

LOST! Gray Tabby Cat. Friendly! May be traveling in wooded area around Ridgedale 36?-1377 ☎ 217-6416

Adopt Me Pets

all your favorites...

Domestic Pets

[illegible]

FREE to good home: mixed breed [illegible] male, very gentle & friendly. ☎ 731-[illegible]

German Rottweiler Puppies: 8 wks. AKC registered. champion blood lines. [illegible]

German Shepherd Pups. [illegible] long haired, shots & wormed. [illegible] Text or call 731-[illegible] or 731-616-4306

GERMAN SHEPHERD pups - [illegible]

▼ HOLLYWOOD PUPPIES ▼ We Raise Our Own! [illegible] Chihuahua, Yorkie Poo, Shihtzu, Pomeranian [illegible] ▶▶ 731-[illegible] ◀◀

YORKIE PUPS [illegible] wks old, CKC reg., parents on site, home raised. [illegible] Male & female. Call 731-[illegible] Serious inquiries only please.

Pet Services

Yorkshire Terrier 4 Years Old. $550. Not neutered, needs family, loves kids! ☎ 762-891-2525 Ask For Diane

On The Farm

all things farming...

Farm Equipment

Case International 1140 Diesel 23HP, hog box, blade and more. [illegible] purchased. $[illegible] ☎ 731-[illegible]

Horses and Ponies

Big Valley 3 Horse Slant, AC & Heat. Good Flooring, HD [illegible], sleeps 2 [illegible], 4 new tires. $3,[illegible] 731-445-[illegible]

Livestock_Poultry

3 reg. Black Angus cows, 4.5 years old. Excellent bloodlines. $1,[illegible] each. (2) 15 mo. old reg. Black Angus bulls, sired by Final Answer, will meet State TAEP. $2,500 ea. ☎ 731-[illegible]

Pigglets for sale, [illegible]

Great Buys Yard Sale

neighborly deals...

Madison Central

Yard Sale, Sat. June 11, 7 A.M. - [illegible] Grandview Dr. Off Parkway near the [illegible] clothes and more stuff! [illegible]

Jackson: MOVING SALE! [illegible] Russell Rd. Sat. 6/11, 7 a.m. Antique Dining Rm, furniture, glassware, cookware, tools & mowers!

RIFA SUMMER WAREHOUSE SALE. [illegible] Airways Blvd, Jackson. Saturday, 6/11, [illegible]. Lots of furniture, appliances (small & large), lamps, books, old records, art work and frames, luggage, linens, jewelry, clothes and shoes.

Madison East

3 Family Sale: [illegible] Dr. across from Trinity Church at the 4 way. 7am-? Cheap and some is Free!

Find your next pet!

Wanted to Buy

APPLIANCES WANTED
Will Buy Non Working Appls.
★★ 731-697-7551 ★★

Madison Central

Estate Sale

Estate Sale of the late Hugh and Maxine Yarbro
1258 Campbell St.
Friday, June 10th, 9-3
Saturday, June 11th, 10-3
Numbers to enter the home on Friday will be given out at 8:30am. Outside sale will begin at 9, inside will begin at 9:30

This week we have an awesome vintage and antique sale. French sofa with matching chair, Duncan Phyfe game table, pie crust end tables, Victorian settee, pump organ, Victorian marble top table, oak sideboard, oak Larkin desk, Dutch German grandfather clock, mantle clocks, oak china cabinet, large Eastlake buffet with marble top and lovely carving, oak buffet with serpentine front, walnut Eastlake full size bed, couple of Eastlake walnut washstands, Eastlake marble top dresser, white painted depression bed with matching dresser, walnut dining table made by Jackson cabinet maker, John Duffey, couple of oak dining tables, 2 sets of six dining chairs, several trunks and cedar chests, oak 5 drawer office desk, oak knee hold office desk, desk chairs, lift chair, Frigidaire refrigerator, Frigidaire 40 inch electric stove, Russel Wright, "Iroquois" china, quilts, linens, glassware, lamps, kitchen misc., and much more.

Outside

Yard tools, metal mesh lawn furniture, ladders, concrete planters, metal shelving, wheel barrow, dinner bell, odd furniture pieces, lots of misc. 1985 Chrysler Fifth Avenue car. The home is for sale by owner and they will be on site to assist you with any information.

See pictures at: www.cestatesales.net
C & C Estate Sales
Calvin and Carla Murphy
731-476-3435

Madison North

2 Family Garage Sale! June 10 & 11, [illegible] Tree Dr. [illegible] (in Three Way area)

2-FAMILY YARD SALE SATURDAY 7-NOON Furniture, household items, kids clothing, [illegible] 24 [illegible], Humboldt

30 Fieldcrest Dr. Sat. June 11, 7am-? Girls [illegible] clothes & shoes, home pictures & etc... And More!!

Don't miss this one!

BIG BIG GARAGE SALE! [illegible] [illegible] EVERYTHING YOU CAN IMAGINE! [illegible]

Friday & Saturday at 7am
24 Farmington Dr. Jackson
Large 2 Family Sale! Furniture, household, clothes, trailer.
★ ★ CHEAP! ★ ★

Garage Sale! Fri. 12-4 & Sat. 7-Noon 40 Yorkshire Cove. (Off Farmington) Bed comforters, pillows, pictures, mirrors, nice Spring ladies clothes

Huge 3 Family Yard Sale! [illegible] Sat. June 11, 7-2 Pictures, lamps, [illegible] Items And More!!

HUGE RUMMAGE SALE Antique & Victorian furniture [illegible] THUR, FRI, SAT [illegible] 1285 CAMPBELL ST. Jackson Between N. Highland & N. Parkway

HUGE YARD SALE! 37 Brookstone Pl. Too Much To Mention. Fri. 7-1pm & Sat. 7-Noon

HUGE YARD SALE!
★ 707 Watson Rd ★
Friday Only, 6am-6pm
Furniture, tools, clothing
Too Much To Mention
☎ 731-694-0459

ESTATE SALE

Milan, TN. 5085 Honeysuckle Ln Saturday June 11th, 11 am - 3 pm [illegible] Furniture, some antiques, [illegible] Come Prepared to take purchases with you and cash is preferred. [illegible]

MOVING SALE! 44 Westend Cove Humboldt, TN Friday [illegible] Rain or shine! Furniture, appliances, clothes, toys, Christmas decor, household items Etc. 731-414-3754 EVERYTHING MUST GO!

[illegible]

Rummage Sale, 25 Canvasback Cove, Saturday, June 11, 7-12, furniture, luggage, Christmas tree, misc. items

Windrake Cove Neighborhood Garage Sale Friday June 10th & Saturday June 11th [illegible]-Jackson

GARAGE SALE

Yard Sale [illegible] Cove, Saturday, June 11, 7 am. Rain or shine. [illegible] [illegible]

Madison South

▶ 2-FAMILY YARD SALE ◀ [illegible] 251 STEAM MILL FERRY RD. SATURDAY JUNE 11, 6AM UNTIL?

Backyard Rummage Sale! 3199 Riverside Dr. ★ Fri. 8-? Sat. 8-12 ★ Firepit, lots of women's clothes & misc. items!

Neighborhood SALE

[illegible] Saturday, June 11, [illegible]

Yard Sale! 461 Old Pinson Rd. Tools, clothes & camping June 10 & 11, 7:30am

Wanted to Buy

Madison South

YARD SALE, [illegible] Sat., 7am-Noon. [illegible]

Madison West

[illegible] 743 US HWY 138 (off Hwy 70 west)

Other Areas

Community Sale

Stonecreek Subdivision ★ Annual Yard Sale, Medina ★ 30 + Residents, Saturday, June 11, 7-?

Assorted Merch

all kinds of things...

General Merchandise

2005 Wildwood camper trailer, 26ft Bunker bed kitchen slide needs repair, $3,950 OBO before 7am (731)695-1458

3 Kennedy Machinist Tool Boxes (1 roller box) incl tools $[illegible] 731-[illegible]

7 DISNEY VHS MOVIES BLACK DIAMOND COLLECTION, CINDERELLA, BEAUTY AND THE BEAST, FOX AND THE HOUND, LITTLE MERMAID, ALADDIN, 101 DALMATIANS, PETER PAN, [illegible] CINDYE [illegible]@YAHOO.COM

★★★ APPLIANCES ★★★ All in great appearance & working cond. Black stove & refrig. $425 Washer $150 / Dryer $125; Side by side Refrigerator, with ice & water. [illegible] Fridge $195 ★★ 731-[illegible], in Jackson ★★

Dining table w/ 6 chairs [illegible]

GARDEN FOUNTAINS [illegible] 2 styles, [illegible] excellent condition, north Jackson. [illegible]

INTERNET WIFI, Verizon [illegible] 4GLTE Mobile Hotspot, north Jackson. [illegible]

Lg. collection of antiques! Approx. 3,000 records & 1 million [illegible], 2,000 vintage [illegible] Civil war items, Call: 731-415-1436

[illegible]

Recliner $[illegible], loveseat $[illegible] [illegible] ★ 731-[illegible]

Sofa, Recliner on each end [illegible] 731-267-[illegible]

Solid Oak bedroom suit [illegible] 731-[illegible]

VICTORY VACUUM [illegible]

Wanted to Buy

WANTED: Looking For Window AC, 2 Room Size And Unit Working Condition Call ☎ 731-928-0657

Want: [illegible] good condition. Reasonably priced. [illegible]-2525, ask for Diane

Your Source Public Notices

for the latest...

Public Notices

0001280397

NOTICE OF ELECTION

The Madison County Election Commission located at 311 N. Parkway is open for registration Monday through Friday from 9:00 a.m. to 4:00 p.m. The phone number is 660-1796. The last day to register in person or to hand deliver forms is July 5, 2016 Applications with postmarks dated later than July 5, 2016 will not be processed before the August 4, 2016 election. Early voting for the August 4th State Primary and and County General Election will be held July 15-30. Early voting will take place at the Madison County Agricultural Complex Auditorium located at 309-C N. Parkway, Jackson, TN. Early voting hours will be from 9:00 a.m. until 4:00 p.m. weekdays and from 9:00 a.m. until 12:00 noon on Saturdays.

Disabled and/or elderly persons who believe that their polling places are inaccessible are encouraged to vote early or may vote at the Election Commission Office on Election Day. Voters who intend to vote at the Election Commission office on Election Day must notify the commission office in writing no later than July 25, 2016.

Phil Bryant, Chairman
Nell Huntspon, Secretary
David Johnson
Mike Bledsoe
Jeanie Todd

Classified Marketplace Where neighbors deal with neighbors.

Continued from last column

0001302558

NOTICE OF PUBLIC AUCTION

A PUBLIC AUCTION WILL BE HELD TO DISPOSE OF ITEMS WHICH HAVE BEEN DECLARED SURPLUS BY THE JACKSON-MADISON COUNTY SCHOOL SYSTEM. INCLUDED IN THE AUCTION WILL BE SCHOOL BUSES, ONE WRECKER, ONE TRACTOR/BACKHOE, OTHER VEHICLES, ETC.,

LOCATION OF AUCTION: JACKSON-MADISON COUNTY SCHOOL SYSTEM BUS GARAGE, 59 HARTS BRIDGE ROAD WEST, JACKSON, TN

TIME & DATE OF AUCTION: 9:00AM, TUESDAY, JUNE 14, 2016

ALL ITEMS MAY BE VIEWED & INSPECTED BY THE PUBLIC BEGINNING AT 8:30AM ON THE DAY OF THE AUCTION.

ALL ITEMS WILL BE SOLD "AS IS" AND WITH NO WARRANTIES IMPLIED OR EXPRESSED, & MUST BE REMOVED FROM SCHOOL SYSTEM PROPERTY WITHIN A REASONABLE TIME AS DETERMINED BY THE SCHOOL SYSTEM'S TRANSPORTATION SUPERVISOR.

MADISON COUNTY GOVERNMENT, NOR ANY OF ITS DEPARTMENTS, OFFICES OR AGENCIES, DISCRIMINATES ON THE GROUNDS OF RACE, COLOR, RELIGION, DISABILITY, SEX, AGE OR NATIONAL ORIGIN.

MADISON COUNTY, TN FINANCE DEPT.,
PURCHASING OFFICE

0001307317

NOTICE IS HEREBY GIVEN

That Penny L Cronin has made an application to the Madison County Beer Commission for a permit to sell beer in Madison County. This application is for an On Premise Permit, located at 2176 Highway 70 East, Madison County, Tennessee.

Said hearing will be held on June 20, 2016 at 8:00 A.M. at the West Tennessee Center for Agricultural Research and Public Service, Conference RM 153, 605 Airways Blvd., Jackson, Tennessee.

Fred Birmingham
Secretary
MADISON COUNTY
BEER COMMISSION

0001307333

REQUEST FOR PROPOSALS
Construction Services
Tennessee
Housing Development Corporation

Proposals are requested by Tennessee Housing Development Corporation (THDC) from firms capable of providing Construction Services to complete new construction and rehabilitation services for housing as well as to participate in the evolution of plans and specifications with the A/E during the design development work for the project. The work is to be conducted at a the existing Kingfield development and on the vacant parcel to the north, located at Kingsfield Drive, just off North Royal Street, Jackson, TN. Submittals will be evaluated according to published criteria. A clearly marked "Construction Services Proposals" in PDF must be received by email at the THDC offices attention Sue Fleming (sfleming@jacksonha.com) by 11:00 am CT on Friday June 24, 2016 in order to be considered.

A PDF of the RFP package is available by emailing Ms. Fleming at the above email address. All persons requesting a copy of the RFP package must provide name, mailing address, telephone and cell numbers, and email address in case any addenda are issued.

There will be a pre-submission conference on Thursday June 16, 2016 beginning at 10:00 a.m. The conference will begin at THDC offices, in the JHA building at 125 Preston, Jackson, TN. Written inquiries may be submitted no later than 2:30 pm, CT, Monday, June 20, 2016. Inquiries may be sent via email to sfleming@jacksonha.com.

All Offerors must be licensed Contractors as required by the Contractors Licensing Act of 1976 9TCA Title 62, Chapter 6) of the General Assembly of the State of Tennessee. There will be a Performance and Payment Bond. The right is reserved to reject any or all bids or to waive any informalities in the procurement process. Because certain financing associated with this development involves Federal funds from the U. S. Department of Housing and Urban Development, certain requirements mandated by HUD regulations will apply and are further outlined in the RFP pack-

Continued to next column

Continued from last column

age.

All packages submitted are subject to the instructions, special conditions and specifications contained therein, all of which are made a part of this Request for Proposals by reference.

0001308824

REQUEST FOR PROPOSALS
Investor Services
Tennessee Housing
Development Corporation

Proposals are requested by Tennessee Housing Development Corporation (THDC) from firms capable of providing Investor Services for Low-Income Housing Tax Credits (LIHTC) and associated lender services. THDC is an "instrumentality" of the Jackson Housing Authority (JHA). The work is for new and rehabbed housing, located at the existing Kingfield development and on the vacant parcel to the north, located at Kingsfield Drive, just off North Royal Street, Jackson, TN. The projects are proceeding under HUD's RAD program. Submittals will be evaluated according to published criteria. A clearly marked "Investor Services Proposals" in PDF must be received by email at the THDC offices attention Misty Gordon (mgordon@jacksonha.com) by 11:30am CT on Thursday June 23, 2016 in order to be considered.

A PDF of the RFP package is available by emailing Ms. Gordon at the above email address. All persons

Continued to next column

Continued from last column

requesting a copy of the RFP package must provide name, mailing address, telephone and cell numbers, and email address in case any addenda are issued. Written inquiries may be submitted no later than 2:30 pm, Monday, June 20, 2016. Inquiries may be sent via email to mgordon@jacksonha.com.

There will not be a pre-submission conference.

0001346925

ALL AMERICAN STORAGE
1654 NORTH PARKWAY
JACKSON, TN. 38301
731-424-5275
AUCTION DATE WED. JUNE 15TH 2016 @ 10 AM
#14- TYLER WEAVER
#25- MILTON MORROW
#38- MARY JOHNSON
#60- JACQUISE MCINTEE
#62 & 68- BRANDY SMITH
#115- JESSICA COLMER
#124- BARABARA HILL
#161- MARCUS ADAMS
#202- CHARLES BETHEA
#216- OLIVIA JOHNSON
#221- CHERITA JUMPER

Real Estate Rentals

great places to live...

Condo-Townhouse

3 BR, 1 BA Townhouse, Available [illegible] [illegible] Contact Linda: [illegible]

Find your next job!

Public Notices

Public Notices

0001348971

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care Facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

WONDERWORD

By DAVID OUELLET

HOW TO PLAY: All the words listed below appear in the puzzle — horizontally, vertically, diagonally and even backward. Find them, circle each letter of the word and strike it off the list. The leftover letters spell the WONDERWORD.

FACIAL FUZZ IS TRENDY — Solution: 12 letters

E	C	E	S	N	R	U	B	E	D	I	S	P	W	P
C	H	L	L	H	O	B	L	I	G	H	T	O	W	I
N	E	C	B	B	A	P	R	I	G	O	R	A	A	L
E	E	I	A	R	B	M	I	I	A	G	J	N	L	R
C	K	L	E	T	U	U	P	L	A	T	C	N	R	E
S	S	L	C	I	S	S	T	O	R	H	K	G	U	W
E	Y	O	A	N	S	U	H	S	O	E	N	C	S	O
L	N	F	F	Y	E	B	O	R	M	I	P	O	U	L
O	R	E	B	M	E	V	O	M	M	I	H	P	A	D
D	T	M	C	A	T	N	A	O	L	T	R	V	U	L
A	O	R	R	K	A	R	O	H	O	I	O	T	S	L
C	H	D	F	E	O	R	O	O	S	M	C	H	O	U
U	S	O	L	I	G	P	M	Z	E	H	A	N	H	F
T	A	C	H	I	N	S	T	R	A	P	G	L	E	Y
S	W	H	I	S	K	E	R	S	E	R	O	P	E	P

 6/10

Adolescence, Anchor, Barely, Beards, Brush, Cheeks, Chinstrap, Clean, Comb, Cuts, Duck, Dutch, Face, Fine, Follicle, Full, Goatees, Grooming, Grow, Hair, Jaw, Light, Long, Lower Lip, Male, Moustache, Movember, Neck, Pencil, Pores, Razor, Removal, Shampoo, Shape, Shave, Sideburns, Smooth, Stubble, Tail, Tiny, Trim, Upper Lip, Walrus, Wash, Whiskers

Yesterday's Answer: Northumberland

STATE GAZETTE

294 US Highway 51 Bypass N.
Dyersburg, TN 38024
731-285-4091
Fax: 731-286-6183

I, Jina Jeffries, business manager of the State Gazette, a newspaper published at Dyersburg, Tennessee, hereby certify that the annexed advertisement has been published 1 consecutive/ non-consecutive days/weeks in said paper on the following dates: 6/10/2016 and that the fee of $ 268.80 has/has not been paid.

Jina Jeffries

This 15th day of June, 2016

SHELIA ROUSE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF DYER

Shelia Rouse, Notary Public

Commission expires: February 14, 2018

CLASSIFIEDS

DEADLINES for Display Ads
Tuesday Friday 4 pm
Wednesday Monday 4 pm
Thursday Tuesday 4 pm
Friday Wednesday 4 pm
Sunday Thursday 4 pm

PHONE: 285-4091 · FAX: 286-6183

We reserve the right to reject any advertisement. We are responsible only for the first insertion of an advertisement. Advertisers are advised to check their ad immediately after it appears in the paper and report at once any errors found.

Legals

Legal 05-3086

NOTICE OF FORECLOSURE SALE

STATE OF TENNESSEE, DYER COUNTY

WHEREAS, Fred William Tilley Jr executed a Deed of Trust to Mortgage Electronic Registration Systems, Inc. As Nominee For Regions Bank D/B/A Regions Mortgage, Lender and FMLS, Inc., Trustee(s), which was dated December 30, 2009 and recorded on January 6, 2010 in Book 712, Page 604-619, Dyer County, Tennessee Register of Deeds.

WHEREAS, default having been made in the payment of the debt(s) and obligation(s) thereby secured by the said Deed of Trust and the current holder of said Deed of Trust, Regions Bank d/b/a Regions Mortgage, (the Holder), appointed the undersigned, Brock & Scott, PLLC, as Substitute Trustee, by an instrument duly recorded in the Office of the Register of Deeds of Dyer County, Tennessee, with all the rights, powers and privileges of the original Trustee named in said Deed of Trust; and

NOW, THEREFORE, notice is hereby given that the entire indebtedness has been declared due and payable as provided in said Deed of Trust by the Holder, and that as agent for the undersigned, Brock & Scott, PLLC, Substitute Trustee, by virtue of the power and authority vested in it, will on June 28, 2016, at 12:00PM at the usual and customary location at the Dyer County Courthouse, Dyersburg, Tennessee, proceed to sell at public outcry to the highest and best bidder for cash, the following described property situated in Dyer County, Tennessee, to wit:

Tract No. 1: Beginning at a point being the southeast corner of a lot heretofore conveyed to the grantees herein as shown by deed of record in Deed Book 121, Page 122 in the Register's Office for Dyer County Tennessee, this point being also in the West margin of Lot 8 and the Eastern margin of Lot 7 of the FAIRFIELD SUBDIVISION; runs thence in a southerly direction with the West margin of Lot 8 and the East margin of Lot 7 of Fairfield Subdivision approximately 550 feet to the southeast corner of Lot 7; thence in a westerly direction with the South margin of Lot 7, 97.4 feet; thence in a northerly direction with the West margin of Lot 7 and the East margin of Lot 6, approximately 550 feet to the southwest corner of the property heretofore conveyed to the Robersons, as above referred to; thence in an easterly direction with the South margin of the property heretofore conveyed to the Robersons 97.4 feet to the point of beginning. Tract No. 2: Being the North portion of Lot No. 7 of The Fairfield Subdivision as shown in Plat Book 1, Page 33 of the Register's Office for Dyer County, Tennessee and being more particularly described as follows: Beginning at a stake in the northwest corner of Lot 7 as shown in the Plat Book cited above; runs thence North 87 degrees 47 minutes East 97.4 feet to a stake runs thence South 1 degree 20 minutes West 200 feet to a stake; thence South 87 degrees 47 minutes West 97.4 feet to a stake; thence North 1 degree 20 minutes East 200 feet to the point of beginning. Tract No. 1 and 2 being known as Parcel 43, Map 122 in the Dyer County Tax Assessor's Office Tract No. 3: Being Lot No. Six (6) of the FAIRFIELD SUBDIVISION as shown by plat of record in Plat Book 1, Page 33 in the Register's Office for Dyer County, Tennessee, to which reference is here made for a more complete description of said lot. Tract No. 3 being known as Parcel 42, Map 122 in the Dyer County Tax Assessor's Office. Being the same property conveyed unto Robert H. Singleton and wife, Mary Linda Singleton by Warranty Deed from Claud B. Roberson and wife, Mary S. Roberson as recorded in the Register's Office of Dyer County, Tennessee at Book 279 Page 339 as recorded on 09/4/92.

Parcel ID Number: 122 043.00 and 122 042.00
Address/Description: 239 Sorrell Chapel Loop, Dyersburg, TN 38024.
Current Owner(s): The Estate of Fred Williams Tilley, Jr.. Other Interested Party(ies): N/A

The sale of the property described above shall be subject to all matters shown on any recorded plat; any and all liens against said property for county property taxes; any restrictive covenants, easements or set-back lines that may be applicable; any prior liens or encumbrances as well as any priority created by a fixture filing; a deed of trust; and any matter than an accurate survey of the premises might disclose; and

All right and equity of redemption, statutory or otherwise, homestead, and dower are expressly waived in said Deed of Trust, and the title is believed to be good, but the undersigned will sell and convey only as Substitute Trustee. The right is reserved to adjourn the day of the sale to another day, time, and place certain without further publication, upon announcement at the time and place for the sale set forth above.

This office is attempting to collect a debt. Any information obtained will be used for that purpose.

Brock & Scott, PLLC, Substitute Trustee
c/o Tennessee Foreclosure Department
6 Cadillac Drive, Suite 140
Brentwood, TN 37027
PH: 615-550-7697
FX: 615-550-8484
File No.: 16-06578 FC01

Publication:
May 27, 2016
June 03, 2016
June 10, 2016

LEGAL 06-3098

PROBATE COURT
JASON HUDSON
PROBATE JUDGE
DYER COUNTY

NOTICE TO CREDITORS

Civil Action No. 16-PR-36

Estate of Ralph E. Buckley

Notice is herby given May 27, 2016 letters testamentary (or of administration as the case may be) in respect of the estate of Ralph E. Buckley died August 24, 2015 were issued to the undersigned by the Probate Court of Dyer County, Tennessee. All persons, resident and nonresident , having claims, matured or unmatured, against the estate are required to file the same with the clerk of the above named court on or before the earlier of the dates prescribed in (1) or (2) otherwise their claims will be forever barred:
(1) (A) Four (4) months from the date of the first publication (or posting, as the case may be) of this notice if the creditor received an actual copy of this notice to creditors at least sixty (60) days before the date that is four (4) months from the date of first publication (or posting) as described in (1) (A); or
(2) Twelve (12) months from the descendent's date of death.
This 27th day of May, 2016.

Administrator or Crystal Buckley Morgan and Joshua Buckley

Attorney for the Estate:
John Palmer
116 Court St. W.
PO Box 746
Dyersburg, TN 38025

Publication dates:
June 10, 2016
June 17, 2016

LEGAL 06-3099

CHANCERY COURT
TONY CHILDRESS
CHANCERY JUDGE
DYER COUNTY

NOTICE TO CREDITORS

Civil Action No. 16-CV-242

Estate of Cleo Ray Lay
Notice is herby given that on the 24th day of May, 2016 letters of testamentary (or of administration as the case may be) in respect of the estate of Cleo Ray Lay who died on April 27, 2016 were issued to the undersigned by the Chancery Court of Dyer County, Tennessee. All persons, resident and nonresident , having claims, matured or unmatured, against the estate are required to file the same with the clerk of the above named court on or before the earlier of the dates prescribed in (1) or (2) otherwise their claims will be forever barred:
(1) (A) Four (4) months from the date of the first publication (or posting, as the case may be) of this notice if the creditor received an actual copy of this notice to creditors at least sixty (60) days before the date that is four (4) months from the date of first publication (or posting) as described in (1) (A); or
(2) Twelve (12) months from the descendent's date of death.
This 24th day of May, 2016.

Personal Representative:
Susan Lay Dew

Attorney for the Estate:
J. Michael Gauldin
113 S. Mill Ave.
PO Box 220
Dyersburg, TN 38025

Publication dates:
June 10, 2016
June 17, 2016

Clerk/Deputy:
H. Steven Walker

Legal 06-3100

INVITATION TO BID

Sealed proposals will be received at the Office of the Purchasing Agent, City Hall, 425 West Court Street, Dyersburg, TN until 1:00 p.m. on 06/22/16 at which time they will be opened for the purchase of the following:
Speed rated police tires
Concrete
Sodium Hypochlorite
Wastehauler tires

Specifications are

NOTIFICATION OF INTENT
TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

The applicant seeks licensure as a Home Health Agency (limited as described above) by the Board for Licensing Health Care facilities. The applicant's principal office will be located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, TN 38137. The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Tennessee Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

Pursuant to TCA Sec. 68-11-1607(c)(1): (A) any health care institution wishing to oppose a Certificate of Need application must file a written objection with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled, and (B) any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

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State Gazette

LETTER OF INTENT -- HEALTH SERVICES & DEVELOPMENT AGENCY

The Publication of Intent is to be published on or before June 10, 2016, for one day, in the following newspapers:

(a) The *Commercial Appeal*, which is a newspaper of general circulation in *Crockett, Fayette, Hardeman, Hardin, Haywood, Lake, Lauderdale, McNairy, Obion, Shelby, Tipton* and *Weakley Counties*;

(b) The *Jackson Sun*, which is a newspaper of general circulation in *Carroll, Chester, Decatur, Gibson, Henderson* and *Madison Counties*;

(c) The *Paris Post-Intelligencer*, which is a newspaper of general circulation in *Benton* and *Henry Counties*; and

(d) The *Dyersburg State Gazette*, which is a newspaper of general circulation in *Dyer County*.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. §§ 68-11-1601 et seq., and the Rules of the Health Services and Development Agency, that AxelaCare Health Solutions, LLC (a proposed home health agency with its principal office in Shelby County), to be owned and managed by AxelaCare Health Solutions, LLC (a limited liability company), intends to file an application for a Certificate of Need to establish a home health agency and to provide home health services exclusively limited to the home infusion of immune globulin pharmaceuticals in the following West Tennessee counties at a cost estimated at $69,628: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton and Weakley Counties.

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The anticipated date of filing the application is on or before June 15, 2016. The contact person for the project is John Wellborn, who may be reached at Development Support Group, 4219 Hillsboro Road, Suite 210, Nashville, TN 37215; (615) 665-2022.

John Wellborn 6-9-16 jwdsg@comcast.net

(Signature) (Date) (E-mail Address)

BASS BERRY + SIMS PLC

W. Brantley Phillips, Jr.
bphillips@bassberry.com
(615) 742-7723

October 13, 2016

VIA HAND DELIVERY

Melanie Hill
Executive Director
Tennessee Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville TN 37243

Re: AxelaCare Health Solutions LLC (CN1606-022)

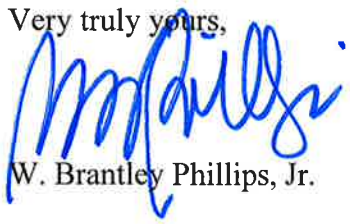
Dear Ms. Hill:

In connection with the above-referenced application, please find attached several letters of support from national research institutions, physician practice groups and patients. Please include this group of support letters in the materials that are provided to the Agency members. We will look forward to being present on October 26th to discuss the many merits of this application.

Thank you for your attention in this matter, and please let us know if you have any questions about the attached.

With kind regards, I remain,

Very truly yours,



W. Brantley Phillips, Jr.

WBP:
Attachment
cc: Michele Hartman Tamene

20628468.1

10/12/2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: AxelaCare Health Solutions LLC (CN1606-022)

Dear Ms. Hill:

I want to express my support for AxelaCare Health Solutions LLC's certificate of need application to expand its services in West Tennessee. From personal experience, I can attest that the work AxelaCare does with patients around the country makes an important and positive contribution to patient care and medical research.

Many rare and complex diseases lack evidence based treatment guidelines. My practice entails the diagnosis and management of such diseases, many of which are treated with IVIg (intravenous immunoglobulin). The increased acceptance and use of home infusions for IVIg creates a unique opportunity to collect and measure patient outcomes data. With AxelaCare's unique "CareExchange" technology, physicians and nurses are able to capture valuable patient data easily and securely. This data offers in site into the way rare disease are diagnosed and treated, thereby improving our understanding of diagnostic and treatment shortcomings. AxelaCare's CareExchange technology also allows physicians to use that data to potentially help understand how any individual patient responds to treatment. This is critically important when attempting to individualize or optimize therapy for rare diseases in which there is no standard long term treatment guideline.

I value the research partnership with AxelaCare, and appreciate efforts they have made to improve patient monitoring during long-term IVIg therapy. I strongly endorse AxelaCare's application for a Certificate of Need. Thank you for your consideration in this matter. Please do not hesitate to contact me with any questions.

Sincerely,

Jeffrey Allen MD
University of Minnesota
Department of Neurology

DeKalb Medical Physicians Group
Neurology Specialists of Decatur

2665 North Decatur Road, Ste 450, Decatur, GA 30033
www.neurologyspecialistsofdecatur.com

ph: 404.501.7555
fx: 404.501.7550

Tamara S. Greene, M.D.

October 11, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: AxelaCare Health Solutions LLC (CN1606-022)

Dear Ms. Hill:

I am a physician at Neurology Specialists of Decatur in Decatur, Georgia and want to express my support for AxelaCare Health Solutions LLC's certificate of need application to expand its services in West Tennessee. From personal experience, I can attest that the work AxelaCare does with patients around the country makes an important and positive contribution to medical research. I am certain that the approval of this project will assist both in improving patient care and the orderly development of healthcare in your state. I urge your agency to approve AxelaCare's application.

Many rare and complex diseases, and the medicines that treat them, lack a robust body of research to support physicians in designing the most effective care plans. By better understanding these conditions and the way they are treated, we can offer hope to patient facing serious long-term medical challenges. The increased acceptance and use of home infusions for IVIg (intravenuous immunoglobulin) create a unique opportunity to collect and measure patient outcomes data with trained clinicians. With AxelaCare's unique "CareExchange" technology, physicians and nurses are able to capture valuable patient data easily and securely. Research institutions like ours rely on this data as we work to study dose response, dose optimization, drug side effects and variations in treatment results across diverse demographic groups and diagnoses. The goals for improved patient outcomes and reductions in costs are put closer within reach thanks to the research support that the data collected from AxelaCare's patients provides.

I value my partnership with AxelaCare, and am confident that the addition of AxelaCare's services in West Tennessee region will enhance our research efforts. For all of these important reason, I enthusiastically endorse AxelaCare's application for a Certificate of Need. Thank you for your consideration in this matter. Please do not hesitate to contact me with any questions.

Sincerely,

Tamara S. Greene, M.D.

Wesley
Neurology Clinic

Center for the Diagnosis, Treatment and Research of Neurological Disorders

Bola Adamolekun, M.D.
Tulio E. Bertorini, M.D.
Yaohui Chai, M.D.
Gregory J. Condon, M.D.
Hafiz A. Elahi, M.D.
Nada El Andary, M.D.
Mark LeDoux, M.D.
Jesus F. Martinez, M.D.
Rekha Pillai, M.D.

Nancy F. Baker
Administrator

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Suite 400
Memphis, TN 38104
(901) 725-8920

East Office
8000 Centerview Pkwy
Suite 305
Memphis, TN 38018
(901) 624-2960

MRI Center
8000 Centerview Pkwy
Suite 101
Memphis, TN 38018
(901) 624-0384

North Office
3950 New Covington Pike
Suite 270
Memphis, TN 38128
(901) 387-2120

wesleyneurology.com

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Wesley Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system--some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

Having companies like AxelaCare that specialize in pharmacy and IgG infusion nursing in the home setting provides a great alternative to treat these patients. Identifying companies that can provide home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed,. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

I support Axelacare's application for a Certificate of Need to provide these specialized services. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Tulio Bertorini M.D.

June 9, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

I am a Registered Nurse working for Memphis Neurology. We are a multi-physician specialty medical practice in Memphis treating patients with disorders related to the nervous system. We see patients from Memphis and several counties surrounding Shelby County.

In the past, we have attempted to identify home health agencies that will treat our patients requiring immune globulin (Ivig) therapy in the home. This is an infused therapy given by IV which requires specially trained skilled nurses to administer. The RN goes to the home, starts an IV, administers the drug and monitors the patient throughout the infusion. Due to the nature of the drug and the dose given, this can often require the infusion to last 4-8 hours and must be given over consecutive days. Consequently, many home health agencies decline these patients because they do not have the trained staff or the number of nurses available to service.

Recently, I have had patients that should have received this therapy in the home but I could not identify an agency in West Tennessee that could service this type of patient.

I am requesting that you approve Axelacare's request for CON to provide services for our patients. There is an unmet need in our area and having Axelacare as an option to provide these services could improve the quality and timeliness of care our patients receive.

Sincerely,

Rivers Collison, RN, BSN

Rivers Collison, RN

May 26, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

Memphis Neurology is a physician specialty medical practice that focuses on disorders related to the nervous system,some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required and their inability to staff experienced Ig infusion nurses as soon as needed,. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Shankar Natarajan, M.D.

Rahul Sonone, M.D.

Neurologists:

Thomas W. Arnold, M.D.

Maroun Dick, M.D.

Kendrick K. Henderson, M.D.

Joshua J. Lennon, M.D.

Barbara Cape O'Brien, M.D.

David L. Pritchard, M.D.

Libong Shen, M.D.

Lee S. Stein, M.D.

Chip Harris, Administrator

Germantown Park

8000 Centerview Pkwy. #300

Cordova, TN 38018

(901) 747-1111

(901) 747-1137 fax

MRI

8000 Centerview Pkwy. #101

Cordova, TN 38018

(901) 624-0384

(901) 309-5160 fax

Sleep Center

8000 Centerview Pkwy. #115

Cordova, TN 38018

(901) 255-7150

Memphis Neuroscience Research Center

8000 Centerview Pkwy. #300

Cordova, TN 38018

(901) 866-9252

(901) 255-1457 fax

Web Site:

www.neurologyclinic.org

Neurology Clinic, P.C.

July 29, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Axelacare Health Solutions LLC--Certificate of Need Application

Dear Ms. Hill:

The physicians and staff at the Neurology Clinic recognize the need for Axelacare Health Solutions LLC's certificate of need application to provide comprehensive, integrated home infusion care to residents of West Tennessee.

Neurology Clinic is a multi-physician specialty medical practice that focuses on disorders related to the nervous system--some of which are chronic conditions that are difficult to address. Often, advanced immune globulin (IgG) infusion therapy is the best treatment alternative. Unfortunately, it can be difficult for many patients (especially rural residents) to use, due to the fact that a treatment regimen can take several days and more than one visit to administer. Such patients would be best served by having access to IgG in their homes, to avoid needless travel.

The number of patients requiring immune globulin infusion is increasing rapidly as the treatment's effectiveness is explored and demonstrated. We are also seeing many health insurance companies requiring patients to be treated in the home setting rather than in the hospital or infusion suites. Those two factors will steadily increase this region's referrals for IgG home infusion.

We need options like AxelaCare that offer specialty pharmacy and IgG infusion nursing in the home setting. Providing timely home infusion therapy for patients who are not able to access infusion suites has been extremely difficult due to the few authorized agencies, their refusal to provide first-infusion home visits, their inability to handle visits longer than 2 hours when required, their inability to staff experienced Ig infusion nurses as soon as needed, and limited ability to transmit real-time clinically detailed and appropriate feedback on our patients' responses during infusion. The latter is available, however, from AxelaCare through its hand-held CareExchange technology. We are also pleased by AxelaCare's willingness to provide home care in all our rural counties, which some providers cannot do.

For these reasons, we support Axelacare's application for a Certificate of Need. Its clinical skills and technology are needed by our patients. Having them as a referral option will improve the quality of home care that we are able to recommend to our patients. Please do not hesitate to contact me with any questions.

Sincerely,

Dr. Kendrick Henderson

NIHA
National Integrated Health Associates
Leaders in Integrative Medicine and Biological Dentistry

5/16/16

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at National Integrated Health Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in Arlington, TN.

National Integrated Health Associates is a specialty medical practice of six physicians and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in Shelby County. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time--and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

Respectfully submitted,

Tracy Freeman, M.D.

Susan Greenberg FNP

Susan Greenberg FNP-BC

5225 Wisconsin Avenue, Suite 402 • Washington, D.C. 20015
(202) 237-7000 www.NIHAdc.com Fax (202) 237-001

INTERNATIONAL
PRECISION MEDICINE
ASSOCIATES

2200 Pennsylvania Avenue NW
4th Floor East Tower
Washington, DC 20037
888-727-6910
Fax 202-765-2456

May 17, 2016

Melanie M. Hill
Health Services & Development Agency
Andrew Jackson Bldg., 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Dear Ms. Hill:

The physicians at International Precision Medicine Associates want to express our support for Axelacare Health Solutions LLC's Certificate of Need application to expand its services to West Tennessee. There is a significant need for access to the valuable services that Axelacare provides, and we are confident that the approval of this project will assist both in improving patient care and the orderly development of healthcare in the region. We urge you to give Axelacare's application your approval. While our physician practice is not in Tennessee, we have a patient who resides in West Tennessee.

International Precision Medicine Associates is a specialty medical practice of two physicians, one naturopathic physician, and nurse practitioners. Our patients are primarily residing in the Maryland, Virginia and Washington DC area, but also live in other areas of the country, including the patient in West Tennessee. Many of our patients are afflicted with challenging medical conditions – such as Primary Immune Deficiency, Selective Ig Deficiency, Common Variable Immune Deficiency – that defy conventional forms of therapy. In such cases, immune globulin infusion (IgG) therapy is often the best, and sometimes, the only, treatment alternative. A treatment regimen can take several days to administer; so it is a burden for many rural patients to have to travel long distances to receive infusions in institutional settings.

The addition of Axelacare home infusion nursing to the West Tennessee region will be a real improvement in our options. Axelacare specializes in IgG home infusion therapy and has been recognized by The Joint Commission for meeting exemplary clinical standards. It has a proven track record of success of delivering IgG therapy in many other states, using its in-house specialty pharmacy and nursing resources, and we would welcome the opportunity to have access to its integrated services (both nursing and pharmaceuticals) for the benefit of our patients. We also value AxelaCare's advanced *CareExchange* technology, which allows us to collect assessment and outcome data on our patients remotely and in real-time--and feel that it is best operated by AxelaCare's own experienced infusion nurses, as proposed in this application. Knowing our patient will receive the same standard of care and clinical outcomes data collection in Tennessee allows us to effectively manage the patient from afar.

For all of these reasons, we enthusiastically endorse Axelacare's application for a Certificate of Need. Axelacare's home infusion nursing services are needed throughout the West Tennessee region, and will improve the quality of care for our patient.

Respectfully submitted,

Charles Gant, M.D., Ph.D.

From: Sandra Frye
Sent: Tuesday, September 09, 2016 10:31 AM

Subject: Recommendation Letter

To whom it may concern, my doctor has ordered that I receive IVIG infusions as I am diagnosed with Myasthenia Gravis.
I am ordered to receive this medication at home. I do receive my infusions at home by a contracted nurse. It would be much
More stream lined if I was able to receive my medication and nursing from one company. My nurse is good but not an IVIG
Nurse. My understanding is that Axelacare nurses are specially trained in IVIG infusions and diseases. If they were licensed
In Tennessee it would make things so much easier for people receiving IVIG.
Sincerely, Sandra Frye.

Recommendation letter for CON approval.

Dear State of TN Board of Nursing,
I have been asked to write a letter recommending that Apelacare obtain a CON so they can provide nursing for Ig patients in the home.

My daughter has Turner's Syndrome and requires Ig every month. The lack of nursing in the area has left her with large gaps of time between infusions due to no one being able to come to our home to infuse her. She works and goes to school so time is precious and infusion suites are not open in the evenings and weekends. I would ask that Apelacare be granted a CON so people like my daughter can receive their Ig and live their lives to the fullest. — Dana Williams - father of Alexis Williams

TN Recommendation Letter for License in the ~~State~~

To Whom it may concern,
I have been going to my doctor to get my IVIG infusions. It is a hardship for me to go due to my condition and I have pain. If Applecare was able to have a license I could get my IVIG at home and it would be so much easier for me. Now there is no nursing that will see me where I live.
It is my wish that Applecare have a license so I can get my medicine at home.

Thanks, sincerely
Mrs. Linda Wren

From: AEC

Subject: Tyler
Date: Tuesday, August 30, 2016 1:29:48 PM

Dear Dennis ,
I wanted to reach out to you to thank you for coordinating care for Tyler's infusion . I understand I will be working with a separate nursing service for awhile until Axelecare can apply for the proper license . I cannot wait for that as Tyler had Axeleacre nursing and pharmacy in one when he lived in Florida. Being able to have all of his care under one roof with one company makes things easier and there is less chance for errors and confusion.
Take care ,
April Cohenour

RULES
OF
HEALTH SERVICES AND DEVELOPMENT AGENCY

CHAPTER 0720-11
CERTIFICATE OF NEED PROGRAM – GENERAL CRITERIA

TABLE OF CONTENTS

0720-11-.01 General Criteria for Certificate of Need

0720-11-.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Agency will consider the following general criteria in determining whether an application for a certificate of need should be granted:

(1) Need. The health care needed in the area to be served may be evaluated upon the following factors:

(a) The relationship of the proposal to any existing applicable plans;

(b) The population served by the proposal;

(c) The existing or certified services or institutions in the area;

(d) The reasonableness of the service area;

(e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, TennCare participants, and low-income groups;

(f) Comparison of utilization/occupancy trends and services offered by other area providers;

(g) The extent to which Medicare, Medicaid, TennCare, medically indigent, charity care patients and low income patients will be served by the project. In determining whether this criteria is met, the Agency shall consider how the applicant has assessed that providers of services which will operate in conjunction with the project will also meet these needs.

(2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:

(a) Whether adequate funds are available to the applicant to complete the project;

(b) The reasonableness of the proposed project costs;

(c) Anticipated revenue from the proposed project and the impact on existing patient charges;

(d) Participation in state/federal revenue programs;

(e) Alternatives considered; and

(f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.

(3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:

(Rule 0720-11-.01, continued)

(a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, the applicant's proposed TennCare participation, affiliation of the project with health professional schools);

(b) The positive or negative effects attributed to duplication or competition;

(c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;

(d) The quality of the proposed project in relation to applicable governmental or professional standards.

(4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, The Agency may consider, in addition to the foregoing factors, the following factors:

(a) Need. The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change to the proposed new site.

(b) Economic factors. The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.

(c) Contribution to the orderly development of health care facilities and/or services. The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.

(5) Certificate of need conditions. In accordance with T.C.A. § 68-11-1609, The Agency, in its discretion, may place such conditions upon a certificate of need it deems appropriate and enforceable to meet the applicable criteria as defined in statute and in these rules.

Authority: *T.C.A. §§ 4-5-202, 68-11-1605, and 68-11-1609.* ***Administrative History:*** *Original rule filed August 31, 2005; effective November 14, 2005.*

CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954

DATE: July 29, 2016

APPLICANT: AxelaCare Health Solutions, LLC
5100 Poplar Avenue, 27th Floor Suite 2739
Memphis, Tennessee 38137

CN1606-022

CONTACT PERSON: John Wellborn
4219 Hillsboro Road, Suite 210
Nashville, Tennessee 37215

COST: $69,628

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:
The applicant, AxelaCare Health Solutions, LLC, located at 5100 Poplar Avenue, 27th Floor, Suite 2739, Memphis, Tennessee 38137, seeks Certificate of Need (CON) approval to establish a home health agency and provide home health services exclusively limited to the home infusion of immune globulin IVIG)pharmaceuticals in Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Lake, Lauderdale, Madison, McNairy, Obion, Shelby, Tipton, and Weakley counties.

The project does not contain major medical equipment or initiate or discontinue any other health service, and it will not affect any facility's licensed bed complements.

The applicant will lease 149 square feet of office space at FMV of $2,797.

AxelaCare Health Solutions, LLC is ultimately owned by UnitedHealth Group Inc. The applicant provides a legal entity and organization chart in Attachment A.4-Ownership.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

NEED:
The applicant's service area contains the following 21 counties:

County	2016 Population	2020 Population	% of Increase/ (Decrease)
Benton	16,672	16,741	6.7%
Carroll	28,380	28,207	-0.6%
Chester	18,260	18,978	3.9%
Crockett	14,884	15,080	1.3%
Decatur	11,963	12,077	1.0%
Dyer	39,306	39,872	1.4%
Fayette	44,637	48,510	8.7%

Gibson	51,394	52,438	2.0%
Hardeman	27,283	27,278	0%
Haywood	18,410	18,128	-1.5%
Hardin	25,557	26,783	0.9%
Henderson	29,349	30,298	3.2%
Henry	33,439	34,055	1.8%
Lauderdale	28,658	29,186	1.8%
Lake	8,299	8,579	3.4%
Madison	103,234	106,352	3.0%
McNairy	27,179	27,760	2.1%
Obion	31,692	31,559	-0.4%
Shelby	959,361	981,022	2.3%
Tipton	67,250	71,196	5.9%
Weakley	36,066	36,360	0.8%
Total	**1,621,273**	**1,660,459**	**2.4%**

Tennessee Population Projections 2000-2020, 2015 Revised UTCBER, Tennessee Department of Health

This project seeks Tennessee licensure and CON approval to establish an integrated AxelaCare home infusion program across all of West Tennessee for patients utilizing AxelaCare infusion medications for immune globulin. The applicant intends to file CON applications for similar programs in Middle and East Tennessee.

AxelaCare Health Solutions, LLC (AxelaCare) is the fourth largest provider of home infusion medications and services. In addition, AxelaCare is a leader in research partnerships in this field of medicine. AxelaCare is accredited by The Joint Commission, and holds The Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (Supporting the project by suppling medications to the home health team) is accredited by URAC, a distinction which it earned with a 100% score on its accreditation surveys.

AxelaCare is both a licensed pharmaceutical company and a home health services provider. The applicant's regional pharmacy is locate in Kansas but has a Tennessee non-resident pharmacy license that allows them to ship immune globulin product to patient homes in any Tennessee county when prescribed by the patient's physician. As a service provider in 17 states (through 33 branch offices) AxelaCare operates a full-scope program that integrates the AxelaCare Pharmacy with AxelaCare clinical teams of pharmacists and skilled home infusion nurses who manage the infusion of the medications in patient's homes as directed by their physicians. AxelaCare nurses and pharmacists are in 17 states were AxelaCare provide services, and are available 24/7 for patient assistance and for consultation with referring physicians, before, during and after the patient's infusion.

Specialty home infusion is the process of providing very specialized medicines intravenously in a patient's home, with the presence of a skilled registered nurse who works under the direction of the patient's referring physician.

AxelaCare is requesting to provide direct services and product for specialty home infusion of its immune globulin medications only. Services would be limited to adult and pediatric patients in 21 contiguous West Tennessee counties, using AxelaCare' s own skilled registered nursing staff. The service will provide infusion of Immune Globulin either directly into the vein or through a subcutaneous site.

AxelaCare is not requesting authorization for infusion of other medications, only one narrow type of specialty infusion, Intravenous Immune Globulin (IVIG).

Immune Globulin is a medicine that contains antibodies, which are tiny proteins that patrol the blood stream to alert the body to germs, which the body can then destroy through a complex immune system. Specialists use IVIG infusions when other therapies have failed. Specialists referring to AxelaCare will most likely be neurologists, immunologists, oncologists, and dermatologists. Specialists use IVIG for peripheral neurology, small fiber neuropathy, Gulliain-Barre Syndrome, Multiple Sclerosis, amongst others. The applicant lists numerous disorders

treated with IVIG on page 12 of the application.

The applicant's sequence of delivery of home infusion care for IVIG patients included:

- Patient and Physician contacts,
- Comprehensive assistance to the patient prior to infusion,
- An initial home visit,
- Preparation for infusion or "Dosing" (a prescribed amount of medication to be administered in a single dosing cycle (a series of from one to five days),
- Care during the infusion sessions,
- CareExchange Technology-a proprietary tech tool that gathers and enters clinical and patient data,
- Use of patient Data for Research.

Many home health agencies are reluctant to provide home infusion services. The highly specialized IVIG service is challenging and unprofitable for almost all home health agencies in West Tennessee. There are several reasons why home health agencies who provided regular home health services seldom offer IVIG.

1). There are risks of adverse patient reactions, especially for the first infusion. Most agencies prefer less complex and more predictable patients.

2). The IVIG infusions require highly skilled infusion registered nurses. Most agencies do not have such staff available at the time it is needed and do not provide staff training required to create a high level of competency in home infusion care.

3). IVIG infusions require the home health nurse to be present and to be highly observant and active in recording patient clinical information for periods of 2-10 hours per session. Few home health agencies want to offer a service that tie up a nurse for that length of time.

4.) The best home infusion care allows for immediate nursing consultation with the referring physicians office and/or pharmacist, during the infusion service. To respond to this need, AxelaCare has developed its own CareExchange technology, which allows its nurses to optimize the accuracy, ease, and speed of gathering information and communication with the physician or pharmacist-both during and after the infusion service.

There are 52 home health agencies approved to serve the 21-county service area, of which two are not currently licensed. The applicant contacted 46 agencies to determine if they currently staffed or had a subcontract in place to provide IVIG without delay. Only one agency was able to provide IVIG home care, while two other agencies were similarly prepared but were only licensed for 6 urban counties in the region.

Coram Alternative Site Services, Inc. (CN1406-018) is the only comparable specialty infusion service in the service area. In 2015, Coram was only in operation from 3/26/2015 to 6/30/2015 in the Joint Annual Report of Home Health Agencies, 2015. During this time period, Coram reported serving 4 patients; 3 from Shelby County and 1 from Fayette County. Coram's total gross revenues for 2015 were $44,285.

Home Health Patients and Need in Service Area

County	# of Agencies Licensed	# of Agencies Serving	2015 Population	2015 Patients Served	2018 Population	Projected Capacity	Projected Need	Need or (Surplus) for 2020
Tennessee	1,635	1,473	6,735,706	170,304	6,962,031	176,109	104,430	(71,679)
Benton	12	11	16,655	684	16,711	686	251	(436)
Carroll	13	13	28,430	1,458	28,298	1,458	424	(1,034)
Chester	13	13	18,076	545	18,633	562	279	(282)

Crockett	12	11	14,845	567	14,982	572	225	(348)
Decatur	15	15	11,939	648	12,029	653	180	(472)
Dyer	9	9	39,155	1,902	39,607	1,924	594	(1,330)
Fayette	21	20	43,631	707	46,608	755	699	(56)
Gibson	14	14	51,119	1,870	51,934	1,900	779	(1,121)
Hardeman	15	14	27,285	920	27,284	920	409	(511)
Hardin	16	15	26,479	1,101	26,680	1,109	400	(709)
Haywood	15	13	18,477	649	18,274	642	274	(368)
Henderson	12	12	29,101	1,209	29,836	1,240	448	(792
Henry	11	10	33,267	1,270	33,771	1,289	507	(783)
Lake	7	6	8,230	357	8,441	366	127	(240)
Lauderdale	14	12	28,529	907	28,930	920	434	(486)
McNairy	14	14	27,019	1,138	27,486	1,158	412	(745)
Madison	18	17	102,429	3,220	104,799	3,295	1,572	(1,723)
Obion	10	10	31,722	1,314	31,625	1,310	474	(836)
Shelby	26	26	953,899	16,269	970,212	16,547	14,553	(1,994)
Tipton	21	19	66,234	1,172	69,239	1,225	1,039	(187)
Weakley	15	15	35,894	1,203	36,300	1,217	545	(672)
Total	**303**	**289**	**1,612,415**	**39,110**	**1,643,929**	**39,748**	**24,625**	**(14,333)**

Source: *Tennessee Population Projections 2000-2018 February 2015 Revision,* Tennessee Department of Health, Division of Health Statistics and the *Joint Annual Report of Home Health Agencies, 2015***

- **Most recent Year of Joint Annual Report data for Home Health Agencies.

The Department of Health, Division of Policy, Planning, and Assessment calculated the need for home health services in the 21-county service area to be a surplus of (14,333).

The applicant projects 45 patients and 1,080 visits in year one and 65 patient and 1,560 visits in year two of operation.

TENNCARE/MEDICARE ACCESS:
The applicant will not participate in the Medicare and TennCare/Medicaid programs.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY:
The Department of Health, Division of Policy, Planning, and Assessment have reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and if the projections are based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Costs Chart is located on page 48 of the application. The applicant's estimate total project cost is $69,628.

Historical Data Chart: There is no Historical Data Chart as this is the initiation of a new home health agency.

Projected Data Chart: The Projected Data Chart for Nursing and Home Office only (Pharmaceuticals Only) is located in Supplemental 1, Additional Information. The applicant projects 45 and 65 patients with 1,080 and 1,560 visits respective in years one and two, with net operating revenues of ($150,413) and ($161,587) each year, respectively.

In the Projected Data Chart for AxelaCare West Pharmaceuticals Only is located in Supplemental 1. The applicant projects 45 and 65 patients with 1,080 and 1,560 visits respective in years one and two, with net operating revenues of $669,727 and $1,088,735 each year, respectively.

In the Consolidated Operations , Nursing Home Office, and Pharmaceuticals, the applicant projects 45 and 65 patients with 1,080 and 1,560 visits respective in years one and two, with net operating revenues of $519,313 and $927,148 each year, respectively.

The applicant's average Charges, Deductions, and Net Charges are as follows:

Average Charges, Deductions, Met Charges, Net Operating Income
West Tennessee Nursing Operations Only

	2017	2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue per Patient	$5,760	$5,760
Average Expected Revenue Per Visit	$240	$240
Average Deduction from Operating Revenue Per Patient	$173	$173
Average Deduction from Operating Revenue Per Visit	$7	$7
Average Net Charge per Patient (Net Operating Revenue)	$5,587	$5,587
Average Net Charge per Visit (Net Operating Revenue)	$233	$233
Average Net Operating Income after Expenses per Patient	($3,343)	($2,486)
Average Net Operating Income after Expenses per Visit	($139)	($104)

Average Charges, Deductions, Met Charges, Net Operating Income
Combined West Tennessee Nursing and Out of State Pharmaceutical Operations

	2017	2018
Patients	45	65
Visits	1,080	1,560
Average Expected Revenue per Patient	$101,760	$101,760
Average Expected Revenue Per Visit	$4,240	$4,240
Average Deduction from Operating Revenue Per Patient	$3,053	$3,053
Average Deduction from Operating Revenue Per Visit	$127	$127
Average Net Charge per Patient (Net Operating Revenue)	$98,707	$98,707
Average Net Charge per Visit (Net Operating Revenue)	$4,113	$4,113
Average Net Operating Income after Expenses per Patient	$15,985	$18,110
Average Net Operating Income after Expenses per Visit	$666	$755

The only specialty infusion-specific comparable charge data is Coram/CVS Specialty Infusion Services (CN1406-018). Coram projected its charges for specialty infusion at $290-$348. In comparison, the applicant projected their charge at $240.

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:
AxelaCare has and expects to develop referral and working relationships with a large number of hospitals, specialty medical practices, and home health agencies in the Memphis and Jackson areas.

The applicant believes the positive benefits of the project outweigh the minimal impact this project will have on the 52 home health agencies serving West Tennessee. AxelaCare's patient volume is less than two-tenths of 1% of the 39,026 patients served by area agencies. Additionally, at the

current two-year rate of increase in the existing agencies caseloads in the service, agencies in the area's caseloads will increase by 3,092 patients by year two of the AxelaCare project.

The project will encourage the movement of IVIG infusion patients out of costlier and less convenient settings where they now have to go in order to get timely start of dosing for their disorders. Their conditions will be managed by specialty-trained infusion nurses, using state-of-the-art information technology that enhances real-time communication between the care team and the patient's physicians.

The applicant projects the following staffing for years one and two below.

AxelaCare Healthcare Solutions-West Tennessee

Position	2017 FTEs	2018 FTEs
Home Care Director-Memphis ½ Time in Office	0.5	05
Account Executive	1.0	1.0
Administrative Assistant	0.5	1.0
Field Positions		
Home Care Director-Memphis ½ in Field	0.5	0.5
Infusion Rn's in Filed	**2.0**	**3.0**
Total	**4.5FTES**	**6.0FTEs**

AxelaCare Healthcare Solutions-West Tennessee-Drug Delivery

Position	2017	2018
Pharmacist	1.0	1.0
Techs	1.0	1.0
Delivery	1.0	1.0
Back Office	2.0	3.0
	5.0 FTES	**6.0 FTEs**

The applicant will seek licensure from the Tennessee Department of Health, Board for Licensing Healthcare Facilities. AxelaCare has a Tennessee non-resident pharmacy license that allows them to ship immune globulin product patient homes in any Tennessee county when prescribed by the patient's physician.

QUALITY MONITORING: AxelaCare is accredited by The Joint Commission, and holds The Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (Supporting the project by suppling medications to the home health team) is accredited by URAC, a distinction which it earned with a 100% score on its accreditation surveys.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

Standards and Criteria

1. **Determination of Need:** In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. This 1.5 percent

formula will be applied as a general guideline, as a means of comparison within the proposed Service Area.

2. The need for home health services should be projected three years from the latest available year of final JAR data.

3. The use rate of existing home health agencies in each county of the Service Area will be determined by examining the latest utilization rate as calculated from the JARs of existing home health agencies in the Service Area. Based on the number of patients served by home health agencies in the Service Area, an estimation will be made as to how many patients could be served in the future.

Home Health Patients and Need in Service Area

County	# of Agencies Licensed	# of Agencies Serving	2015 Population	2015 Patients Served	2018 Population	Projected Capacity	Projected Need	Need or (Surplus) for 2020
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Crockett	12	11	14,845	567	14,982	572	225	(348)
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Dyer	9	9	39,155	1,902	39,607	1,924	594	(1,330)
Fayette	21	20	43,631	707	46,608	755	699	(56)
Gibson	14	14	51,119	1,870	51,934	1,900	779	(1,121)
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Hardin	16	15	26,479	1,101	26,680	1,109	400	(709)
Haywood	15	13	18,477	649	18,274	642	274	(368)
Henderson	12	12	29,101	1,209	29,836	1,240	448	(792
Henry	11	10	33,267	1,270	33,771	1,289	507	(783)
Lake	7	6	8,230	357	8,441	366	127	(240)
Lauderdale	14	12	28,529	907	28,930	920	434	(486)
McNairy	14	14	27,019	1,138	27,486	1,158	412	(745)
Madison	18	17	102,429	3,220	104,799	3,295	1,572	(1,723)
Obion	10	10	31,722	1,314	31,625	1,310	474	(836)
Shelby	26	26	953,899	16,269	970,212	16,547	14,553	(1,994)
Tipton	21	19	66,234	1,172	69,239	1,225	1,039	(187)
Weakley	15	15	35,894	1,203	36,300	1,217	545	(672)
Total	**303**	**289**	**1,612,415**	**39,110**	**1,643,929**	**39,748**	**24,625**	**(14,333)**

Source: *Tennessee Population Projections 2000-2018, February 2015 Revision,* Tennessee Department of Health, Division of Health Statistics and the *Joint Annual Report of Home Health Agencies, 2015***

- **Most recent Year of Joint Annual Report data for Home Health Agencies.
-

The Department of Health, Division of Policy, Planning, and Assessment calculated the need for home health services in the 21-county service area to be a surplus of (14,333).

4. **County Need Standard:** The applicant should demonstrate that there is a need for home health services in each county in the proposed Service Area by providing documentation (e.g., letters) where: a) health care providers had difficulty or were unable successfully to refer a patient to a home care organization and/or were dissatisfied with the quality of services provided by existing home care organizations based on Medicare's system Home Health Compare and/or similar data; b) potential patients or providers in the proposed Service Area attempted to find appropriate home health services but were not able to secure such services; c) providers supply an estimate of the potential number of patients that they might refer to the applicant.

   The applicant submitted several letters of support from area physicians who cite the need for the project, due to difficulty of finding home health providers in the service are who are able and willing to respond timely to their patients' needs with the level of care AxelaCare proposes to provide.

5. **Current Service Area Utilization:** The applicant should document by county: a) all existing providers of home health services within the proposed Service Area; and b) the number of patients served during the most recent 12-month period for which data are available. To characterize existing providers located within Tennessee, the applicant should use final data provided by the JARs maintained by the Tennessee Department of Health. In each county of the proposed Service Area, the applicant should identify home health agencies that have reported serving 5 or fewer patients for each of the last three years based on final and available JAR data. If an agency in the proposed Service Area who serves few or no patients is opposing the application, that opponent agency should provide evidence as to why it does not serve a larger number of patients.

   The applicant provided three years of JAR patient data for every home health agency with authorization to provide care in the 21 county service area.

   The applicant identified existing agencies that served five or fewer patients in the service are during each of the past three years. The applicant provides this information in Supplemental Table 2, Supplemental 1.

6. **Adequate Staffing:** Using TDH Licensure data, the applicant should document a plan demonstrating the intent and ability to recruit, hire, train, assess competencies of, supervise, and retain the appropriate numbers of qualified personnel to provide the services described in the application and document that such personnel are available to work in the proposed Service Area. The applicant should state the percentage of qualified personnel directly employed or employed through a third party staffing agency.

   Based on AxelaCare experience and demonstrated quality in 17 states through 33 branch offices, AxelaCare anticipates no problems in attracting superior staff for this project. Implementation of the project will require between 3 or 4 skilled care nurses with documented competencies in infusion care.

7. **Community Linkage Plan:** The applicant should provide a community linkage plan that demonstrates factors such as, but not limited to, referral arrangements with appropriate health care system providers/services (that comply with CMS patient choice protections) and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems. A new provider may submit a proposed community linkage plan.

   The applicant's primary linkage will be referring specialty physicians. AxelaCare will regularly call on area specialty physician groups who serve patients with potential needs for IVIG. AxelaCare will meet monthly with physicians who refer patients to them, to review and discuss patient outcome data and confer on future treatment options.

   The secondary linkage will be to area hospital's discharge planners and medical staff. AxelaCare representatives will be in regular communication with these groups to ensure their awareness of treatment options.

8. **TennCare Managed Care Organizations (MCOs) and Financial Viability:** Given the time frame required to obtain Medicare certification, an applicant proposing to contract with the Bureau of TennCare' s MCOs should provide evidence of financial viability during the time period necessary to receive such certification. Applicants should be aware that MCOs are under no obligation to contract with home care organizations, even if Medicare certification is obtained, and that Private Duty Services are not Medicare certifiable services. Applicants who believe there is a need to serve TennCare patients should contact the TennCare MCOs in the region of the proposed Service Area and inquire whether their panels are open for home health services, as advised in the notice posted on

the HSDA website, to determine whether at any given point there is a need for a provider in a particular area of the state; letters from the TennCare MCOs should be provided to document such need. See Note 2 for additional information.

Not applicable

Applicants should also provide information on projected revenue sources, including non-TennCare revenue sources.
The applicant's gross revenues will be 98% from multiple commercial insurors. The applicant will not be serving Medicare or Medicaid patients.

9. **Proposed Charges:** The applicant's proposed charges should be reasonable in comparison with those of other similar agencies in the Service Area or in adjoining service areas. The applicant should list:

    a. The average charge per visit and/or episode of care by service category, if available in the JAR data.

        The applicant provides this information of page 34 of the application.

    b. The average charge per patient based upon the projected number of visits and/or episodes of care and/or hours per patient, if available in the JAR data.

        The only specialty infusion-specific comparable charge data is Coram/CVS Specialty Infusion Services (CN1406-018). Coram projected its charges for specialty infusion at $290-$348. In comparison, the applicant projected their charge at $240.

10. **Access:** In concert with the factors set forth in HSDA Rule 0720-11-.01(1) (which lists those factors concerning need on which an application may be evaluated), the HSDA may choose to give special consideration to an applicant that is able to show that there is limited access in the proposed Service Area for groups with special medical needs such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. Pediatrics is a special medical needs population, and therefore any provider applying to provide these services should demonstrate documentation of adequately trained staff specific to this population's needs with a plan to provide ongoing best practice education. For purposes of this Standard, an applicant should document need using population, service, special needs, and/or disease incidence rates. If granted, the Certificate of Need should be restricted on condition, and thus in its licensure, to serving the special group or groups identified in the application. The restricting language should be as follows: CONDITION: Home health agency services are limited to (*identified specialty service group*); the expansion of service beyond (*identified specialty service group*) will require the filing of a new Certificate of Need application. Please see Note 3 regarding federal law prohibitions on discrimination in the provision of health care services.

    The applicant intends to provide home health services exclusively limited to the home infusion of immune globulin IVIG)
    pharmaceuticals (IVIG).

11. **Quality Control and Monitoring:** The applicant should identify and document its existing or proposed plan for data reporting (including data on patient re-admission to hospitals), quality improvement, and an outcome and process monitoring system (including continuum of care and transitions of care from acute care facilities). If applicable, the applicant should provide documentation that it is, or that it intends to be, fully accredited by the Joint Commission, the Community Health Accreditation Program,

Inc., the Accreditation Commission for Health Care, and/or other accrediting body with deeming authority for home health services from CMS.

AxelaCare is accredited by The Joint Commission, and holds The Joint Commission's Gold Seal of Approval for the quality of its programs. AxelaCare's National Pharmacy Program (Supporting the project by suppling medications to the home health team) is accredited by URAC, a distinction which it earned with a 100% score on its accreditation surveys.

12. **Data Requirements:** Applicants should agree to provide the Department of Health and/or the Health Services and Development Agency with all reasonably requested information and statistical data related to the operation and provision of services and to report that data in the time and format requested. As a standard of practice, existing data reporting streams will be relied upon and adapted over time to collect all needed information.

    The applicant so agrees.

Notes

1. Professional Support Services and Personal Support Services: It should be noted that an entity providing either "professional support services," as defined by TCA § 68-11-201 (regarding nursing and occupational, physical, or speech therapy services provided to individuals with mental retardation or developmental disabilities pursuant to a contract with the state agency financially responsible for such services), or "personal support services," as set forth in the Rules of the Department of Mental Health and Substance Abuse Services Office of Licensure Chapter 0940-05-38 (regarding self-care assistance, household assistance, personal assistance to access community activities, and education services), does not require a Certificate of Need in order to be licensed by the appropriate department to perform its services.

2. TennCare Medicare Certification: As of the effective date of these standards and criteria, the Rules of the Bureau of TennCare ("TennCare"), the state of Tennessee's Medicaid program, require that any applicant for a Certificate of Need to provide home health services that desires to contract with TennCare's MCOs become Medicare-certified. The process of becoming Medicare-certified can take several months if an agency does not meet Medicare "deemed certified" status through accreditation by national accrediting organizations.

It should be noted that as of the effective date of these standards and criteria, Private Duty Services do not qualify as a Medicare reimbursable service. Thus, an entity that applies for a Certificate of Need should not apply to provide only Private Duty Services if it intends to try to contract with the MCOs as it will not be able to receive Medicare certification. Additionally, applicants should contact TennCare for specific information regarding the ability to contract with MCOs. On the Health Services and Development Agency website (http://www.tn.gov/hsda/) an informational letter is available entitled "Are you thinking about applying for a CON to provide Home Health or Private Duty Nursing Services in Tennessee?"

3. Services not to be Discriminatory in Nature: Some past applications have endeavored to provide home health services to specific populations. It should be noted that federal law prohibits health care providers from providing health care services that discriminate against any population in the areas of race, color, national origin, disability, or age. This prohibition is enforced by the Office for Civil Rights to ensure that eligible persons have equal access to quality health care regardless of race, color, national origin, disability, or age.